Anticipated Acquisition by Cochlear Limited of the hearing implant division of Demant A/S

Response to CMA Issues Statement

20 February 2023

This submission is made by Cochlear Limited ("**Cochlear**" or the "**Acquirer**") and Demant A/S ("**Demant**" or the "**Seller**", together with Cochlear the "**Parties**") in response to the CMA's issues statement published on 20 January 2023 (the "**Issues Statement**"). Defined terms are the same as those used in the Issues Statement unless otherwise specified.

1. COUNTERFACTUAL 2
   A. Demant's exit is rational and inevitable 2
   B. The Seller's decision-making process 6
   C. The absence of any alternative buyer 6
   D. Consequences if the Transaction is not approved 8

2. MARKET DEFINITION 8

3. NO REALISTIC PROSPECT OF ANY SUBSTANTIAL LESSENING OF COMPETITION (SLC) 12
   A. The hearing implants segment is inherently underserved 12
   B. The barriers to market penetration and the need to educate HCPs and promote clinical trials in order to ensure that hearing implants reach the patients who would be better treated by them. 13
   C. Trivial implant volumes and lack of scale 13
   D. The ubiquity of hearing aids across the hearing loss spectrum 13
   E. The availability of other hearing solutions 14
   F. Closeness of competition – the Target is a diminishing competitor in bone conduction implants 16
   G. There is no "market" for passive bone conduction implants 16
   H. Med-El is a significant competitive constraint 18
   I. The Target is not a competitive constraint 20

4. DRIVERS OF INNOVATION 21

5. COUNTERVAILING BUYER POWER 22

6. ENTRY AS A COUNTERVAILING FACTOR 24

7. RELEVANT CUSTOMER/PUBLIC HEALTH BENEFITS 24

Baker McKenzie.

1. Counterfactual

1.1 The Parties reiterate that the relevant counterfactual for an assessment of the Transaction is not the prevailing conditions of competition. The Seller has announced publicly that it is leaving the hearing implants market. Given the loss-making nature of the Target business and the inability to profitably split it up and retain parts of it, it is likely that the Seller would have exited its hearing implants business absent the Transaction. There is no alternative purchaser that could meet the required duty of care owed to Oticon Medical's (the "**Target**") patients. As such, the appropriate counterfactual for the CMA to consider in assessing the Transaction is that (1) the Seller would on the balance of probabilities have inevitably exited the hearing implants segment while maintaining some limited activities (in-house or outsourced) in order to provide continued support to its installed base of patients, and (2) there is no more suitable any alternative purchaser that would be able to take on obligations to provide continuous lifetime support to the Target's installed patient base or to make the necessary investments in R&D and in obtaining regulatory approvals to ensure the cross-compatibility of the Target's installed implants with the latest processors and platforms in a manner which provides ongoing and future support and upgrades to patients.

A. Demant's exit is rational and inevitable

1.2 The Parties contest the CMA's phase 1 findings that it would have been commercially irrational for Demant to discontinue the entire hearing implants business without fully exploring other options given that parts of the business were generating profits and worth almost GBP 100m. This is due to a constellation of factors that are unique to the market for hearing solutions and that need to be considered holistically in order to understand the competitive dynamics that have led to Demant's decision to exit.

1.3 **It is erroneous to equate the purchase price with the value of the assets transferring.** The purchase price in this Transaction is the amount that the Acquirer was willing to pay to (1) protect its investments in upholding the reputation of the hearing implants sector in terms of quality and commitment to life-long patient care, and (2) increase scale and thereby generate better clinical evidence needed to drive wider adoption of hearing implants, bolster efforts to educate and train healthcare professionals ("**HCPs**"), as well as generate efficiencies in terms of regulatory and clinical-related costs. Building trust with patients and hearing HCPs is at the core of the Acquirer's long-term strategy to grow demand for hearing implants so that more patients have better access to the therapies that best meet their individual medical needs. It should also be noted that [✂].

1.4 **It is entirely rational for the Seller to discontinue the entire hearing implants business.** The Seller is a global healthcare and technology group and its core business is the supply of hearing aids, a market with many large competitors that is fiercely competitive. Hearing aids are also highly innovative products, with hearing aid manufacturers having to spend significant volumes on R&D in order to develop competitive products.[1] The hearing implants part of the Seller's business was added as the result of a number of small acquisitions more than a decade ago and brought together under the Oticon Medical banner. The Target's annual revenues amounted to 3% of Demant's total revenues in calendar year 2021. The Seller's Board concluded that continued investment in a loss-making business was an unwelcome distraction from the core hearing aids business in terms of costs, management time, and risks, particularly given the requirement to provide lifetime support to implant patients. The Seller's decision to exit was a strategic choice.

1.5 **Despite years of significant investments, the Target has been consistently loss making.** This is due

[1] For example, R&D expenses for Sonova (approximately 3.4 billion Swiss franc – https://report.sonova.com/2022/app/uploads/01_Sonova_AR_2021_22_Full_Report_en.pdf); WS Audiology (approximately EUR 2.4 billion – https://wsa-cdn-wsapublic.azureedge.net/-/media/images/wsa/2022/wsa_annualreport_2021-22_final.pdf?rev=3c8a157ab5be436ab23e8297534a359f&hash=2BDFF417AB21440B7E1DA3CAF8A611AF); ReSound (approximately 1.4 billion Danish Krone – https://ml-eu.globenewswire.com/Resource/Download/014e01bb-0e45-42e7-bd5f-f714eaa2cae6).

to various factors:

(a) **The Target's cochlear implants business is effectively** [✂]**.** Since entering the cochlear implants segment when the Target acquired Neurelec, a small French manufacturer in 2013, the Target has failed to gain any traction in cochlear implants and has in fact lost market share, including in the "home" market of France. In addition, the Covid-19 pandemic effectively stopped all but the most urgent hearing implant surgeries which had a severe impact on the Target, even before a product recall in 2021. The CMA rightly concluded at phase 1 that the Target is not a competitive constraint in cochlear implants, today or in the future, and this finding holds true across all markets.

(b) **The Seller's hearing implants business has incurred persistent operating financial losses**. The Target recorded losses in 2021 amounting to GBP [✂].[2] The Seller's largest shareholder is a non-profit Foundation that directly or indirectly holds 55-60% of the shares; this structure explains why the Seller had continued to invest in the loss-making hearing implants business for much longer than would ordinarily be expected. The Target's cochlear implants business has been loss making since it was acquired in 2013, and the Target's bone conduction business is not profitable (and would not be profitable) on a standalone basis. Those losses are a reflection of the Target's lack of scale. To be sustainable, the Target's Executive Board concluded that it would have needed to reduce Target's R&D spend and its global distribution costs by approximately [✂]% which was simply not feasible and would only have compounded its relative weakness as a competitive constraint.

(c) **The Target's products lag behind those of its rivals on many product performance metrics, and this gap has increased over time.** As the CMA recognised in its phase 1 decision,[3] in the hearing implants segments the ability to innovate is the key parameter of competition, more so than price. Significant investments of resources and time are required to develop new, innovative products which suppliers rely on to be able to demonstrate added value not only over competitor hearing implant products but also over other more prevalent hearing solutions, including hearing aids. This is a prerequisite in order to qualify for reimbursement, and to convince patients and HCPs to move away from traditional hearing aids. After a decade of significant investment in hearing implants, the Target business had never been "first to market" with a key innovation and could not deliver products that had additional quality, cost, or price benefits over existing competing technologies. This problem would only accelerate as competitors continue to conduct R&D into totally implantable cochlear implants which are recognised to be a significant innovation and in which the Target [✂]. In particular, the Target's R&D has focused on sound processor technology – which has synergies with its wider hearing aids business – but its implant technology research has been [✂]. The Target's bone conduction development project is [✂] compared to the Acquirer's existing solution and [✂] with Med-El's solution.

(d) **The Target's profitability in passive percutaneous bone conduction systems is overstated: this part of the business is not sustainable on its own.** The Target's 2021 audited accounts noted an operating profit (EBIT) of DKK [✂] (approximately GBP [✂]) on a revenue of DKK [✂] (i.e., approximately a [✂]% margin) for the bone conduction business. This operating profit does not reflect the significant resources and staff that are provided from the Seller's core hearing aid business to its bone conduction solutions business. In addition, the total shared capacity cost paid by the cochlear implants business is approximately DKK [✂]. In the short-term, a significant proportion of these costs would persist which would likely result in the

[2] This loss was exacerbated by, but not solely caused by, the Neuro Zti recall; to reiterate, the Target business has been loss-making since the acquisition of Neurelec in 2013.
[3] CMA phase 1 decision, paragraph 143.

Target's bone conduction solutions business being unprofitable.

1.6 The market transition from passive to active bone conduction systems represents a paradigm shift in three critical aspects that heavily influenced the Seller's decision to exit:

(a) First, it entails a move from a Class 2 to a Class 3 medical device which significantly raises the bar on reliability, internal quality assurance procedures, and the requirement to comply with the new EU Medical Device Regulation ("**MDR**"). The approval process for Class 3 is more onerous and costly, with a more intense verification and validation exercise. The Seller's internal documents acknowledge that the [✂].[4] In addition, please refer to Annex 271 – a technical assessment booklet issued by BSI, the only approved body in the UK. As per Annex 271:

(i) In respect of Class 3 implantable devices, a clinical evaluation consultation procedure is required (unless an exception applies) and surveillance may be required thereafter if any modifications to the device adversely affect the risk-benefit ratio. This requires the submission of documentation for review by expert panels. There is no such requirement for Class 2B implantable non-WET (well-established technology) devices.

(ii) Certain Class 3 implantable devices also require a consultation process under the MDR requiring engaging with national competent authorities. This requirement does not apply to Class 2B implantable non-WET devices.[5]

As a result, regulatory application costs are significantly higher for Class 3 compared to Class 2.[6] This difficulty will be compounded by the requirement for separate UK approval from 2024 under the UK Conformity Assessment model.

(b) Second, bringing the Target's active bone conduction solution to market would have required the Seller to maintain relevant know-how and its Class 3 approved manufacturing site in Nice which would [✂] reduce the gross margin of the Target's bone conduction business if it were to operate on a standalone basis, even before factoring in the real costs associated with the cross-subsidisation from the Seller described above.

(c) Third, the transition to active, transcutaneous systems means (i) lost synergies with the Seller's main hearing aids business and, more importantly, (ii) the bone conduction business will take on the key feature of the cochlear implant business in that patients will need lifelong support. Deciding to enter the active transcutaneous segment is a critical strategic decision that requires taking on a commitment to support patients for life: surgeons and clinics look to suppliers that can be relied upon for the long-term to avoid subjecting patients to unnecessary surgeries because their implants are no longer supported by improved sound processors.

1.7 **Sentio is a stranded asset as the Seller is not prepared to make the lifelong commitment to support future potential patients.** There would be a significant impact on the Demant brand and its core hearing aids business if it were to implant patients without the strategic commitment to support them for their lifetime. The Target initially had high hopes for its Sentio active bone conduction solution that it has been developing for the past decade. But the product launch that was anticipated in [✂] was [✂]. The Sentio product has yet to [✂] or receive any regulatory clearance. The Seller concluded that the investment and resources needed to bring Sentio to market were [✂] more than anticipated and, given

[4] Annex DMT-V4-0006676, slide 2. See also, Annex DMT-V2-0024666, slide 8.

[5] The entry into force of that Regulation has also meant that the Target has had to make a major effort to ensure that its older products are also compliant or risk losing authorisation by 2024.

[6] As a reference, and using the costs of regulatory approval in the EU, the cost for the Acquirer seeking regulatory approval in the EU for its Kanso 2 CI sound processor (a Class 3 product) was approximately [✂], while the cost for seeking regulatory approval in the EU for two Baha products (Baha 6 Max, and Baha 5 Power sound processors – each of which are Class 2) was approximately [✂]. The Acquirer notes that there is a similar cost discrepancy in respect of seeking US regulatory approvals. Please also refer to Annex 381, which sets out in further detail the requirements under the MDR and its impact on the Target business.

the absence of synergies between an active solution and the Seller's hearing aid business, and the need to maintain implants specific competencies, the Target would be [✂] even if they could bring the product to market. In addition, the Seller could anticipate challenges in being selected for procurement frameworks because, if approved, [✂]. In its phase 1 decision, the CMA points to a handful of Seller internal documents considering that Sentio had the "*potential to contribute to Demant's growth*" and that some *"successful trials of Sentio*" had taken place; these references do not in themselves provide any evidence that Sentio will be brought to market. The reference to active bone conduction solutions as a "*main growth driver*" relates to the growth of the bone conduction solution segment, rather than Sentio's contribution to Demant's growth.[7] More generally, while the Seller's internal documents track the development of Sentio (as they would for any ongoing R&D), they show that Sentio has continued to [✂] and its eventual launch remains highly uncertain.[8]

1.8 **Demant's exit is inevitable.** The Seller's decision to exit the business was publicly announced in April 2022. That announcement was well received by investors who confirmed Demant's weakness as a distant fourth player after an unsuccessful decade-plus long excursion into the implants segment, with an equity report from Jarden noting that the Transaction "*highlights the plight of subscale manufacturers*" and that "*[f]rom a BAHA perspective, this segment competes in the hearing aid market, of which BAHA represents a very small segment*".[9] Please also refer to the following analysis from Oddo BHF and Morningstar:

> "The complexity of cochlear implants is enormous. Synergies exist only from a sound processing perspective and the distribution to hospitals differs compared to hearing aids. Hence, as the devices are implanted, they are subject to much stronger medical and regulatory risks. The current halt of sales of cochlear implants due to a loss of hermeticity at some implants describe the inherent risk pretty well in our view. Hence, **it is our view that it would have taken many years until the segment would reach breakeven**"
>
> *Oddo BHF, 27 April 2022*

> "Demant's announcement of the sale of its medical segment to Cochlear **ends the firm's unsuccessful decade-plus long excursion into the implants industry** … Demant will receive DKK 850 million for this segment, which … is **nowhere close to recoup the amount of capital the firm deployed** to attempt getting a foothold in implants. Demant has been a **distant fourth player in this space**, and despite the new product introductions hasn't been successful in growing its market share"
>
> *Morningstar, 27 April 2022*

1.9 Since the announcement in April 2022, HCPs have understood that Demant is exiting and the market has moved on. The rationale for the Seller's decision to exit the hearing implants business has been communicated publicly, internally, and in external customer and investor presentations.[10] The Target's status as a discontinued operation is expressly mentioned in the Seller's subsequent financial reports and reflected in its accounts.[11]

1.10 As Demant's President and CEO explained during the initial meeting with the CMA in September 2022, and at the Seller Site Visit in January 2023, there is no turning back. The Seller's exit from the hearing implants segment will occur regardless of the outcome of the merger control processes underway, leading to a wind-down of its activities [✂] and resulting in a worse outcome for its patients as compared with the situation if the Transaction proceeds. It is more likely than not that Demant will be unable to find an alternative purchaser with the resources and commitment to meet the required duty of care to all the Target's existing patients.

---

[7] Annex DMT-V1-0016362, slide 30.
[8] See, for instance, Annex DMT-V1-0018965, pages 1-3 and Annex DMT-V4-0006689.
[9] Annex 358 – Jarden (4).
[10] See, for example, Document DMT-V1-0021187 (an investor presentation relating to the Transaction dated 27 April 2022), Document DMT-V1-0021343 (a roadshow presentation provided by the Seller to customers, prepared in May 2022) and Annex 197 – Seller Investor Relations Presentation – April 2022 (a presentation presented by Søren Nielsen (President & CEO, Seller) and René Schneider (CFO, Seller) on a webcast).
[11] Please see Annex 199 – Seller Interim Report 2022 and Annex 200 – Seller Interim Management Statement, May 2022.

Baker McKenzie.

B. The Seller's decision-making process

1.11 The factors listed above led the Seller to conclude that the size of the profit pool for hearing implants, the constraints applied by national health systems, and the demands and expectations of HCPs, make it difficult for the market to sustain a fourth player that does not bring significant qualitative, cost or price benefits. The Target could not deliver those benefits. It therefore determined to exit the business. But in so doing, it was reluctant to abandon its installed patient base. The Seller's preference was to find a solution that would ensure the best lifelong support for the sake of its patients and for the sake of its reputation as a manufacturer of other hearing technologies. This is not a market where a player can ethically announce – either internally or externally – that they are exiting or have in fact exited without a solution in place. This would only be a last resort.

1.12 In addition, the Seller sought a solution that protected it from future claims: if an unreliable buyer were to subsequently renege on continuing to support the installed base or otherwise exit without guaranteeing such support, customers would invariably seek redress from the Seller.

1.13 The Seller has a two-tiered board system made up of an Executive Board which is responsible for the day-to-day management of the business, and a Board of Directors with eight non-executives. The decision to exit was was made by the Seller's management (the Executive Board) and was endorsed by the Board of Directors. To avoid the risk of leakage and further destabilisation of the Target business given that, [✂], the Executive Board strongly believed that before presenting the exit decision to the Seller's Board of Directors, it was necessary to present an orderly exit strategy. This would reassure both the Target's employees and its customers (including HCPs) that the business has a sustainable future.

1.14 The Executive Board therefore undertook a thorough review of options for divesting the Target responsibly. In particular, the Executive Board sought to identify a true partner who would take over the Seller's obligations with respect to the Target's implanted patients and be willing and able to undertake the significant R&D efforts to make this possible through the adaptation of products to ensure backwards compatibility of the buyer's processors with the Target's implants.

1.15 The Executive Board was adamant that the decision to exit remain strictly confidential until a viable solution that protected patients could be presented to the Seller's Board of Directors and subsequently to the market. These drivers explain the paucity of documentation around the decision to exit as well as the straightforward and swift exercise to find a suitable buyer. The Seller's Board of Directors subsequently authorised the Executive Board (and more specifically the Seller's CEO, Søren Nielsen) to initiate discussions with other hearing implant manufacturers. For economic and technological reasons, the Seller concluded that the Acquirer was the only viable purchaser. The other industry players approached were uninterested or unwilling to take on obligations to the Target's installed patients or to make the necessary investments in R&D and in obtaining regulatory approvals to ensure the cross-compatibility of the Target's installed implants with the new owner's latest processors and platforms.

1.16 The Parties reiterate that given this backdrop the CMA should also take into account the broader context around the Seller's decision to exit the market rather than solely relying on contemporaneous documentary evidence.

C. The absence of any alternative buyer

1.17 In view of the above, the Parties note that, absent the Transaction, the Seller would have exited the hearing implants market and, on the balance of probabilities, there is no alternative purchaser with the resources and willingness to meet the duty of care owed to the Target's patients. The CMA in its phase 1 decision pointed to the sales process run by the Seller and relied on this to establish that there could

be an alternative, less anti-competitive buyer to the Acquirer.[12] As noted above, there was a genuine need to keep the decision to exit confidential until a solution was found. As such, it was not feasible for the Seller to operate a public or open bidding or auction process; had the Seller run such a process, it would have severely undermined the confidence of HCPs and patients in using the Seller's hearing implants (and hearing implants in general) insofar as they would have been extremely reluctant to implant patients with lifetime products in circumstances where a manufacturer has publicly announced it is exiting without a long-term solution to support such patients. The Seller had a strong sense of responsibility to ensure that its patients continue to receive the best lifelong technical and functional support. Exiting without an adequate solution would severely impact the credibility of the Seller (and the industry more generally).

1.18 There are no alternative more suitable buyers capable of safeguarding the interests of the Target's installed patient base and able to make the loss-making business sustainable in the long run. The pool of potential acquirors was inherently small given the structural loss-making nature of the Target and the subscale nature of the hearing implants segment.

1.19 With their deep knowledge of the sector, the Executive Board concluded that there was no business case for any M&A consultant or investment banker to pitch the Target to any non-specialist industry or financial buyer. This view was endorsed by the Board of Directors. The reasons non-industry specialists or financial investors were not considered appropriate buyers can be summarised as follows:

(a) Companies outside the industry would be highly unlikely to succeed in maintaining the required level of care for the Target's patients (assuming they would have been interested in purchasing the Target in the first place), not least given that other larger multinationals have in the past tried and failed to successfully enter the much larger (and technologically much simpler) hearing aids market, including 3M, Siemens, Bosch, Philips and Johnson & Johnson.

(b) Hearing aid manufacturers who were not active in the hearing implant segment would also not have the necessary competencies, resources or distribution network to provide the necessary continuum of support to the Target's patients, nor the competencies, experience or willingness to take on the additional burden of manufacturing and seeking regulatory approval for Class 3 devices.

(c) No financial buyer would be prepared to make the R&D investment necessary to support the Target's installed patient base or to take on the Target's obligations vis-à-vis patients. Any financial sponsor would ultimately look to exit which would be antithetical to the Seller's aims and, as noted above, could leave it open to future claims. In any event, this was not seen as a likely or viable option considering that a leveraged buyout would be too challenging and that a buy-and-build strategy was simply not feasible. The Parties do not agree with the CMA's finding that the bone conduction solutions business is one that attracts "*significant investor interest*"[13] as investors are generally unwilling to commit for the long term to support patients on a lifetime basis.

1.20 Only those already active in the supply of hearing implants could realistically acquire the Target whilst ensuring that the Target's patient base is supported in the longer term. As explained in Annex 133, the Target was marketed through direct outreach by Søren Nielsen (CEO, Demant A/S) to relevant key decision-makers at the main hearing implant suppliers, i.e., [✂].

(a) [✂] declined to participate. [✂] the first company to pioneer active bone conduction systems, is deliberately not present in the passive (percutaneous) segment of the market because it considers passive systems to be an unfit solution, leaving patients with a metal abutment

[12] CMA phase 1 decision, paragraph 74.
[13] CMA phase 1 decision, paragraph 66(a)(ii).

protruding from their skull (the "Frankenstein product") that will always be an unhealed permanent wound with the care complications that go with that. Further, as a family-owned firm, it is not clear that they would have the ability to care for the Target's installed base of cochlear implant patients.

(b) In respect of [✂], the CMA in its phase 1 decision stated that [✂] had expressed some interest in the Target's bone conduction solutions business but that "this interest was not pursued by Demant"; the Parties submit that it is not accurate. [✂].A partial offer for the bone conduction solutions business would have left the Seller's cochlear implants patients stranded and was therefore not a viable solution. In any event, no formal offer was ultimately received. There were no further exchanges beyond the initial indication of interest and it is therefore inappropriate to rely on the "possibility" that [✂] could have acquired part of the Target as a basis to conclude that there could be an alternative, less anti-competitive purchaser.[14]

(c) As a result, the offer from the Acquirer was the [✂] received by the Seller.

1.21 It is more likely than not that Demant would have failed to identify an alternative and suitable purchaser capable of maintaining the Target's duty of care to all of its patients. The acquisition of only the bone conduction solutions business would have left cochlear implant recipients stranded in the future which the Seller sought to avoid at all costs. Non-industry specialists would not satisfy the suitable purchaser test, not least because of the necessity to offer lifelong patient support as a precondition to building trust that is essential for any successful market player. The Target's lack of scale and the unsustainability of its bone conduction assets on a standalone basis are further factors that rule out the emergence of a credible more suitable purchaser.

1.22 The truncated sales process leading to the current Transaction was fully adequate given the specificities of the hearing implants sector and the market failures (described at section 2 below) that explain the Target's demise.

D. Consequences if the Transaction is not approved

1.23 If the Transaction is not approved and in the likely absence of an alternative purchaser, the Seller will close its cochlear implants business and [✂].

1.24 The Seller will discontinue its activities within bone conduction solutions, including [✂]. The Seller will discontinue Sentio, its active bone conduction product currently under development, and will not launch such product as the Seller is neither willing to make the investments required to finalise the product development and approval process nor is it prepared to make the lifetime commitment to patients that this entails, in particular since the decision to exit the cochlear implants business eliminates any potential synergies between the two businesses including the possibility to share Class 3 facilities.

1.25 There may be some [✂] activities in passive bone conduction sales provided [✂]. [✂]. These [✂] activities would be against the backdrop of the rapid shift from passive percutaneous bone conduction products to active transcutaneous bone conduction products (where the Target is not present).

1.26 The Seller's installed patient base will be [✂].

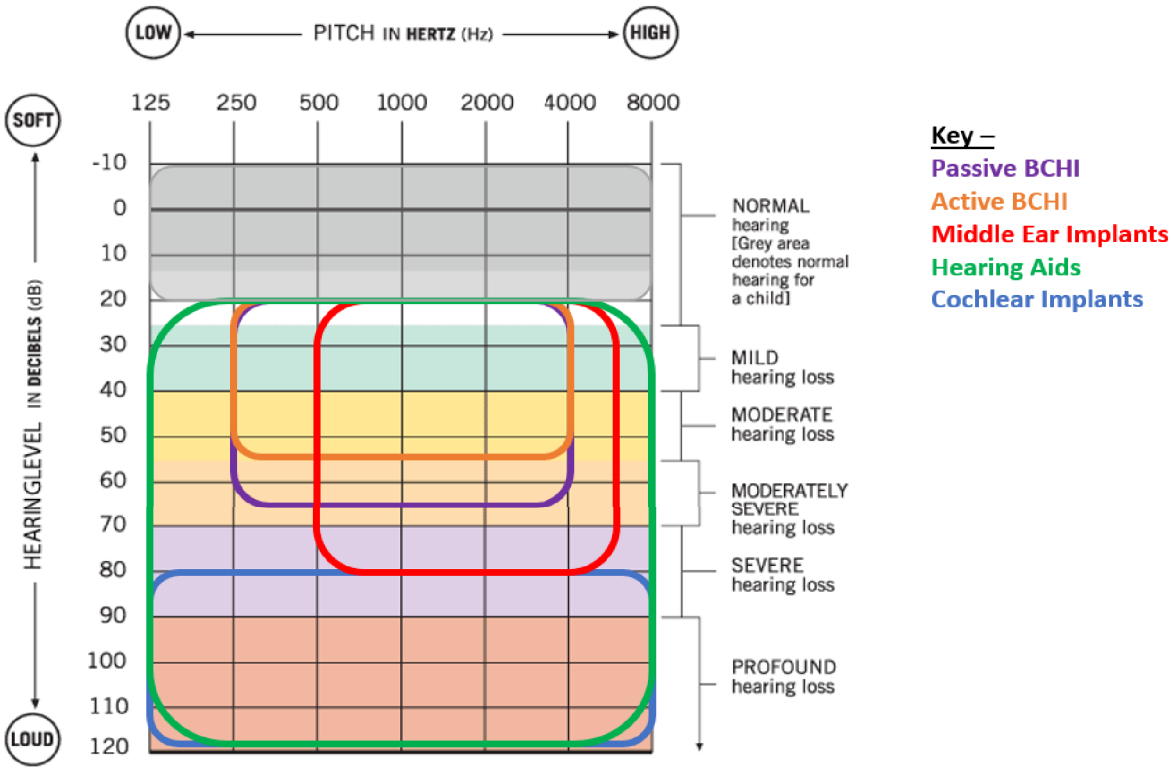
1.27 In light of the above, there is a strong public interest aspect to be considered in terms of the future long-term well-being of the Target's installed patient base.

2. Market Definition

2.1 **The Parties contest the CMA's phase 1 findings that other hearing solutions are not good alternatives for bone conduction implants.** The CMA in phase 1 failed to consider other hearing

[14] [✂].

solutions beyond an observation that competitors have indicated that "*there may be a very small proportion of patients for whom (superpowered) hearing aids may be an alternative to both CI and BCS*".[15] It is also incorrect to say that bone conduction products typically seek to correct more serious hearing loss that hearing aids address; the approved indications of fitting ranges for hearing aids goes significantly beyond that for passive and active bone conduction solutions. Standard hearing aids (and a wide range of other solutions) are an effective alternative for practitioners and public health systems. Please see the below audiogram illustrating the indications and fitting ranges of hearing devices options available to patients.[16]



2.2 Very few patients are recommended bone conduction implants over hearing aids, even when the former offers them a better solution. It does not follow that hearing aids do not offer those patients any clinical value. It is not the case that those patients opting for bone conduction surgery have no alternatives. The nature, degree and progression of hearing loss, along with other factors (such as underlying health conditions) can determine the clinical profile of an individual and the potential treatment options. Even people with the same clinical profile can have very different hearing care needs due to contextual factors such as communication needs, environmental factors, and access to solutions. The severity of hearing loss depends on a number of factors (including type and degree), and once a person has been identified or diagnosed with an ear or hearing condition, there is a range of clinical interventions and technological solutions available, of which hearing implant solutions are a small part. Hearing aids cover the entire range of hearing loss. Hearing aids are getting better, are low cost, and do not require surgery. Please see the below chart previously provided to the CMA which reiterates that bone conduction solutions are

[15] CMA phase 1 decision, paragraph 87.
[16] This audiogram has been prepared with reference to current UK guidance. It is noted that air conduction thresholds from -10dB – 20dB would be classed as "normal" hearing when reviewed by a professional, as such, the fitting ranges of hearing solutions are available for those persons with hearing thresholds of above 20dB.

Baker McKenzie.

significantly overshadowed by hearing aids (or by patient inaction), across all degrees of hearing loss:

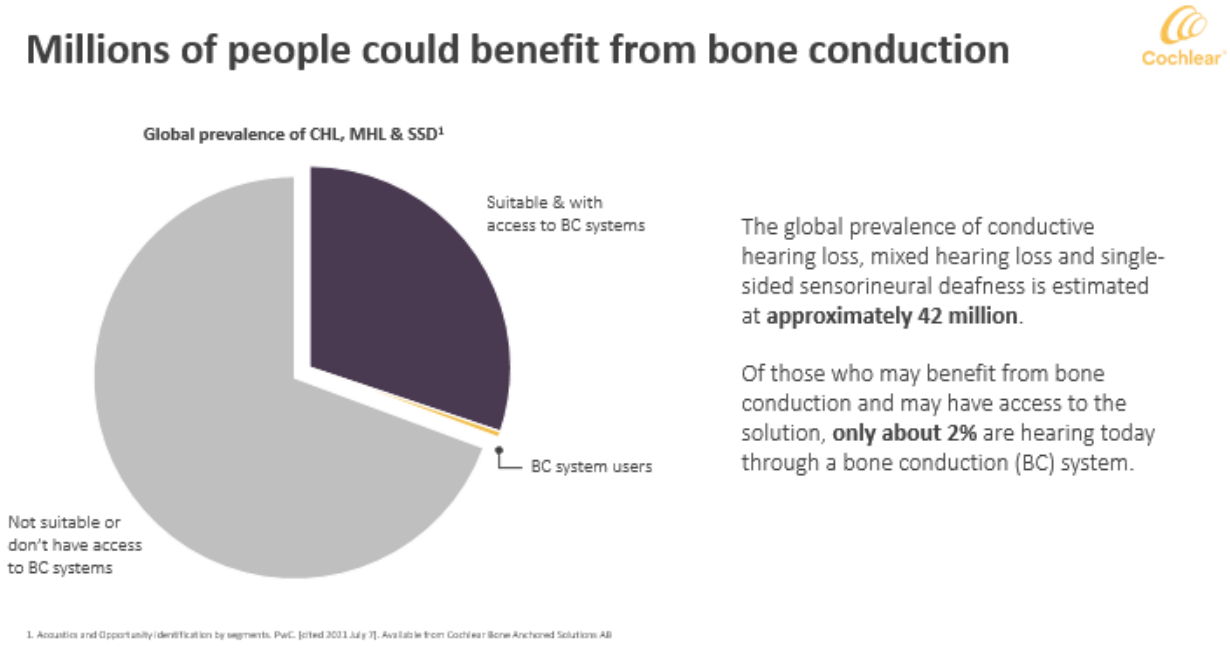
Degree of hearing loss	UK – 2019			
	People with hearing loss	Hearing Aids	Bone conduction solutions	Cochlear implants
Total	*12,534,000*	*2,212,396* ***(17.65%)***	*17,814* ***(0.14%)***	*18,771* ***(0.15%)***
Mild HL (20-34 dB)	8,258,000	503,738 (**6.10%**)	1,652 (**0.02%**)	–
Moderate HL (35-49 dB)	3,369,000	1,078,080 (**32.00%**)	10,107 (**0.3%**)	–
Moderately Severe HL (50-64 dB)	592,000	397,232 (**67.10%**)	5,920 (**1.00%**)	–
Severe HL (65-79 dB)	27,000	21,735 (**80.50%**)	135 (**0.50%**)	756 (**2.80%**)
Profound HL (80-94 dB)	129,000	114,552 (**88.80%**)	–	7,095 (**5.50%**)
Complete HL (95+ dB)	156,000	97,032 (**62.20%**)	–	10,920 (**7.00%**)

2.3 In considering whether the product frame of reference should include other types of hearing solution, the CMA in its phase 1 decision relied on the fact that while hearing aids do not require a patient to undergo surgery, hearing implants do. But in doing so, it failed to consider that this is not a significant difference: bone conduction surgery (both passive and active) can be conducted under local anaesthetic and under thirty minutes (see paragraph 3.30 below for further detail). In any event, the need for surgery for hearing implants reinforces the reality that hearing aids are a constraint because it is easier for HCPs and patients to rely on them rather than implants.

2.4 Whilst bone conduction implants initially cost more than hearing aids (although the difference in lifetime costs is likely to be far smaller), implant suppliers are also significantly constrained by this, and by the pace of innovation in the much larger hearing aids market. The CMA in phase 1 also did not sufficiently take into account the nature of patient pathways and in particular bone conduction referral pathways in the UK, with the NHS England commissioning policy stating that (i) the preferred method of rehabilitating hearing loss is to use conventional hearing aids, and that (ii) patients must trial a conventional hearing aid or a wireless CROS hearing aid for a minimum of 4 weeks, or a non-surgical solution for a minimum of 14 days, before a surgical bone conduction solution product is even considered.[17]

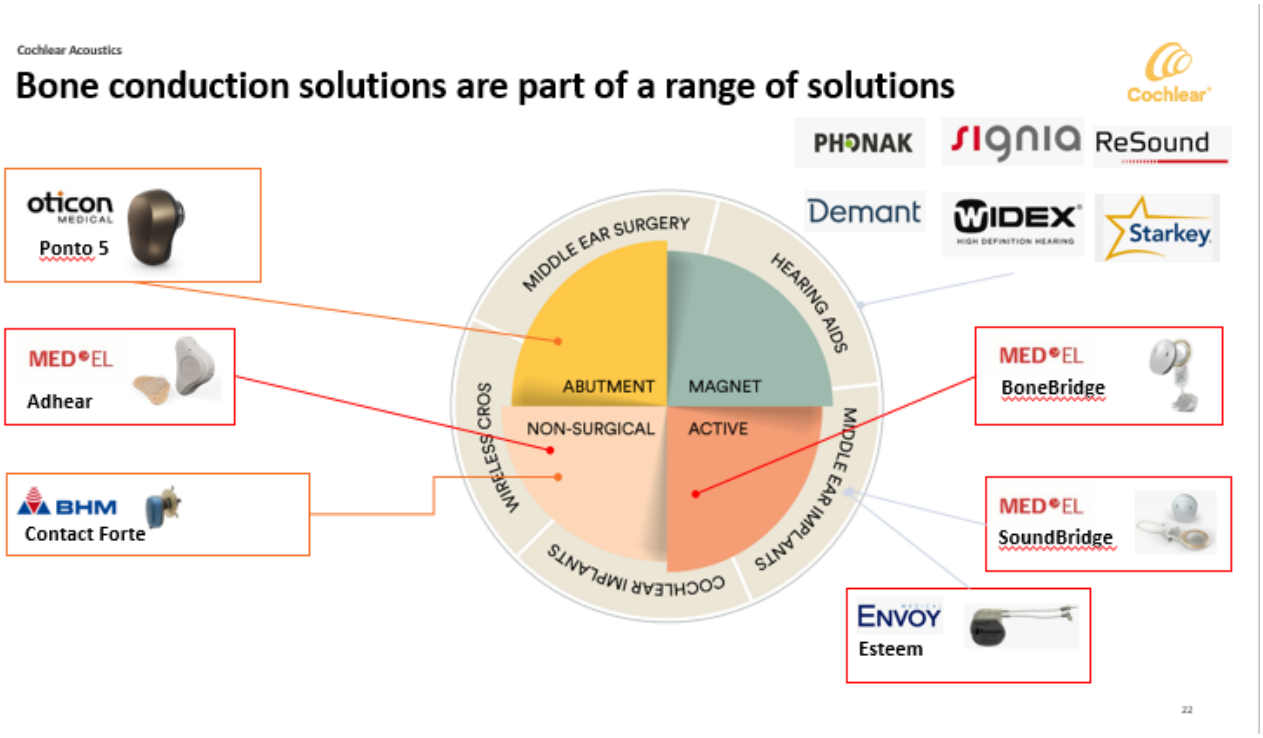
2.5 The Parties estimate that bone conduction's penetration rate is less than 2% globally of all candidates eligible for a bone conduction solution. For the lucky few who are referred for a bone conduction solution, that solution may be optimal for them, but it is nonetheless important to understand that there is no patient for whom a bone conduction implant is the only solution.

[17] https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2013/05/16041_FINAL.pdf.



2.6 The CMA also failed in phase 1 to consider any of the other solutions (such as reconstructive surgery, middle-ear implants, wireless CROS aids, and non-surgical bone conduction solutions), either in the frame of reference or as an out-of-market constraint. It reached the erroneous conclusion that the small and underserved nature of the hearing implants segment is not relevant to the assessment of substitutability between the solutions. The reality is that the hearing implants segment remains small and underserved precisely because there is a range of solutions, because of the ubiquity of hearing aids, because there is a market failure in educating HCPs, and because each patient has differing needs and options. These factors have prevented the hearing implants sector from achieving scale which explains why the Target has failed and why the Seller is exiting. This is reflected in the Acquirer's rationale for the Transaction which is to protect patients who would otherwise be harmed or left unsupported by the Seller's exit and to increase investment in bone conduction solutions to enable that segment to better compete with alternative treatments and improve patient access.[18] It is also reflected in the internal documents of the Parties which repeatedly consider that they operate in a market where the most significant alternatives include patients who do nothing, hearing aids and other forms of hearing solution, not just other hearing implants and that innovation is often driven by these market dynamics.[19]

[18] The CMA noted in its phase 1 decision at paragraph 25 that the Acquirer's internal documents broadly support this strategic rationale.
[19] See, for instance, Annex 022 – [✂], page 5; Annex 011 – [✂] FY22-26, page 19; Annex 010 – [✂]for Financial Years 2022-2026, pages 7, 9, 14, 24 and 29; Annex 109 – [✂]– 2021; Annex 015 – [✂]2021; Annex 221, pages 6 and 9; Annex 222, page 10; Annex 223, page 12; Annex 231, page 15; Annex 235, page 5; Annex 237, page 13; Annex 228; Annex 230, page 9.



2.7 Whether these are qualified within the frame of reference or as out-of-market constraints by the CMA, the fact is that a unique constellation of factors – (i) the vast underserved nature of demand, (ii) the barriers to market penetration, (iii) the trivial implant volumes and lack of scale, (iv) the ubiquity of hearing aids across the hearing loss spectrum, and (v) the availability of other hearing solutions, including reconstructive surgery – combine to ensure that the merged entity will have no market power such that there can be no threat of any SLC. These elements are discussed further below.

3. No Realistic Prospect of any Substantial Lessening of Competition (SLC)

3.1 The CMA is focusing on the bone conduction segment and, specifically, on whether the Target's efforts to launch an active bone conduction implant already acted as a competitive constraint incentivising Acquirer to innovate in order to defend against such a threat.

3.2 The Acquirer's strategic priority is to grow the hearing implant segments of the hearing solutions market, primarily by taking market share from hearing aid manufacturers – and from reconstructive surgery in the case of bone conduction solutions – in order to better address unmet patient needs by reaching patients who would be better treated by a hearing implant. The Target's unsuccessful efforts to launch an active bone conduction solution did not drive the Acquirer's innovation in this segment; the development of the Acquirer's active bone conduction solution began in 2008 prior to the Seller entering the hearing implants segment with its passive percutaneous solution in 2009.

3.3 The nature of the market, the countervailing constraints, and the diminishing role of the Target, means that there is no realistic prospect that the merged entity would be able to profitably raise prices or degrade non-price aspects of its competitive offering (such as quality, range, service and innovation) post-merger.

A. The hearing implants segment is inherently underserved

3.4 Hearing implant value and volume are tiny compared to the ubiquity of hearing aids and market penetration is an uphill battle in competing against other forms of hearing solutions. Reliability, credibility, reputation and innovation are key. Hearing aids – which are used for even the most profound

degrees of hearing loss – remain the default treatment for the overwhelming majority of patients who actually receive any treatment (since a large number of patients suffering hearing loss remain untreated). Among the candidates who could be eligible for a bone conduction solution, bone conduction penetration globally is estimated at only 1-2%.[20] There is therefore a significant opportunity for growth in hearing implants that account for a small proportion of the total global revenues generated from hearing solutions, especially relative to hearing aids. The growth potential is therefore a key motivation for hearing implant suppliers and a powerful competitive constraint today and will remain a powerful constraint on the merged entity (even if growth in demand has been slow to materialise given the challenges described below and the added stresses on the NHS budget following the pandemic).

B. The barriers to market penetration and the need to educate HCPs and promote clinical trials in order to ensure that hearing implants reach the patients who would be better treated by them.

3.5 Currently, there is no clear hearing implant referral pathway in any market. When HCPs and patients do reach a stage of considering hearing implants as an option, there are a range of options available and the clinics can and do switch between different hearing implant suppliers and other solutions, surgical and non-surgical. As such, notwithstanding that the hearing implants segment is inherently underserved, increasing awareness of their benefits amongst audiologists and patients is a long, slow process and has not yet translated into significant growth, despite the sector's spend on innovation and education.

3.6 The Acquirer has led the way with significant investments in education, clinical evidence and external studies to raise awareness and increase HCP confidence; these are long-term strategies and any returns are many years down the line in particular as a result of the small scale of clinical trials and evidence available to the Acquirer.

3.7 This market failure is fundamental to understanding the rationale for the Transaction, why the Target has failed, and why the Transaction does not give rise to a SLC.

C. Trivial implant volumes and lack of scale

3.8 Please refer to Annexes 202 and 210 (for the Acquirer), Table 1 of the Seller's response to the CMA's section 109 notice dated 21 December 2022 and Annex 5.1 to the Seller's response to the CMA's section 109 notice dated 10 January 2023 (for the Target) for a breakdown of their sales of bone conduction solutions in the UK from 2019 to end of 2022. For reference, the Parties combined sold less than [✂] bone conduction implants in calendar year 2022. These very small volumes, coupled with the range of alternative hearing solutions and the fact that no patient is reliant solely on bone conduction implants means that the merged entity has no conceivable market power in the declining passive bone conduction implants subsegment.

D. The ubiquity of hearing aids across the hearing loss spectrum

3.9 For both cochlear implants and bone conduction solutions, there are multiple, simultaneous constraints upon hearing implants suppliers, in particular from hearing aids. Hearing aids – which are used for even the most serious degrees of hearing loss – remain the default treatment for the overwhelming majority of patients. Hearing aids are widely available, affordable, and require no surgical intervention. The prevalence of hearing aids is also reflected in patient pathways, with individuals suspected of having hearing loss being provided conventional air conduction hearing aids for up to three months for a trial; this often prevents patients and HCPs even considering hearing implants as an alternative option. As noted at section 1.4 above, hearing aid manufacturers spend significant amounts on R&D (vastly exceeding that of those active in hearing implants) including in respect of performance, features, connectivity, remote care, apps, and miniaturisation; as noted above, it is this innovation which drives those active in the hearing implants segment. For instance, the Acquirer refers to strategic product briefs

[20] Annex 022 – Target Bone Conduction Business Plan, page 5.

provided in respect of its [✂] and which note:

(a) In respect of a [✂],[21] that:

(i) A key business objective is to [✂];

(ii) That "*[i]ndirect competitors are mainly hearing aids who are setting a standard on what patients expect in terms of size, sound quality, connectivity, battery autonomy, rechargeability and fitting experience*";

(b) In respect of [✂] over conventional hearing aids or over doing nothing about their hearing loss;[22]

(c) In respect of [✂], that a key business objective is to [✂] "*[t]he main indirect competitor are high power hearing aids where patients may choose this over bone conduction as surgery is not needed. In most markets hearing aids are not reimbursed* [✂] *from HA's to secure reimbursement*";[23]

(d) In respect of a project aiming to deliver an [✂] that "*[t]hrough experience, we know that what happens in the Hearing Aid industry today, will* [✂]. *Therefore,* [✂] *are of particular interest*" and a table comparing [✂] from [✂];[24]

(e) In respect of a project relating to [✂]"*As of now, no other company on the bone conduction space offers a service with a similar value proposition. However, most of the big hearing aid manufacturers have both synchronous and asynchronous remote services Hearing Aid industry, none of our direct competitors in the bone conduction space offer it*";[25] and

(f) In respect of a further project on [✂], providing examples of claims for hearing industry [✂] including from hearing aid manufacturers and Med-El.[26]

3.10 The growth of the bone conduction solutions segment would be at the expense of hearing aids and reconstructive surgery. The Parties' internal documents and studies commissioned by Acquirer make clear that [✂] when it comes to considering implants as a solution, even where hearing implants may secure better outcomes. This is exacerbated by findings that HCPs are unaware of or insufficiently educated around hearing implants as an option.

3.11 Taking market share from the hearing aid segment is challenging and it is this dynamic that drives innovation and competition in the hearing implants segments. Furthermore, the Acquirer submits that the constraint is asymmetric, i.e. given the widespread prevalence and ubiquity of hearing aids, bone conduction solutions are not strong competitive constraints on hearing aids but hearing aids are a strong constraint on bone conduction solutions.

E. The availability of other hearing solutions

3.12 Bone conduction solutions are a tiny sub-set of a broader range of hearing products that treat mild to moderately severe hearing loss. For the avoidance of doubt, there are no patients for whom bone conduction solutions are their only option. Largely due to lack of knowledge on the part of HCPs and patients, the vast majority of patients will either take no action and live with the condition unaided or will use a hearing aid even if they could significantly benefit from a hearing implant. When the Parties consider competition in "the market", it is with all the overlapping options (and in particular hearing

[21] Annex 235, pages 2 and 5.
[22] Annex 231, page 7.
[23] Annex 237, pages 3 and 13.
[24] Annex 228, pages 4 and 5.
[25] Annex 230, page 9.
[26] Annex 233, page 10.

aids) in mind, as illustrated by the audiogram provided at paragraph 2.1.

3.13 The Parties' view of the market from a strategic and marketing perspective considers the broader hearing solutions sector, rather than hearing implants in isolation.[27] Bone conduction solutions are a sub-set of a broader range of acoustic hearing products which deliver acoustic signals, with "acoustics" including standard hearing aids, CROS hearing aids, middle-ear implants and non-surgical bone conduction solutions. Acoustic hearing products are suitable for patients across the whole spectrum of hearing loss, though the vast majority of relevant patients who opt for acoustic hearing technology receive hearing aids.

3.14 **Reconstructive, or middle-ear, surgery** remains a predominant treatment, particularly from the perspective of specialised surgeons who are predisposed to "fix" a problem with surgery rather than relying on hearing aids or implants. For instance, in respect of competitors for its Osia system, an internal document of the Acquirer noted: "*The main competitor for the Osia System except "doing nothing" is middle ear surgery and/or* [✂]. *The Osia system must be competitive regarding all these alternatives. We must prove that the hearing outcome and clinical burden are better for the Osia System compared to middle ear surgery*".[28]

3.15 **Middle-ear implants** are a strong competitor product to bone conduction solutions in that they can also be used to treat sensorineural, conductive and mixed hearing loss and have a significantly broader fitting range compared to active and passive bone conduction solutions. Med-El is considered to be a [✂]and is the primary provider of middle-ear implants through its Soundbridge product (which has a fitting range to 75-80dB). Middle-ear implants have important advantages over bone conduction implants in terms of "side specificity", allowing patients to have a better directional sense of where sound is coming from. US company Envoy Medical also has a middle-ear product (Esteem) and is a potential entrant.

3.16 **CROS hearing aids** are a competitive constraint on bone conduction solutions for patients with single-sided deafness ("**SSD**"). CROS-hearing aids have a microphone on one side and a receiver unit on the opposite side – the receiver microphone picks up sound from the impaired side and transmits it via the receiver to the hearing side. These are the prevalent option from a cost perspective and also because of the difficulties in proving the added benefit of bone conduction in a clinical setting where the patient's good ear is able to pick up the sound.[29]

3.17 **Non-surgical products are advancing.** Med-El's ADHEAR non-surgical product is a "new to world" sound processing unit that sits on a small adhesive pad on the soft tissue behind the ear. It uses vibration to send the signal through the bone and is suitable for patients with conductive hearing loss, especially in the paediatric segment. ADHEAR is also suitable for adult use. BHM Tech (an Austrian company) is another company active in non-surgical bone conduction solutions with its "Contact Forte" and "Contact Mini" products. The constraint posed by ADHEAR and BHM Tech is noted in the Acquirer's internal documents (with comments on the latter focusing on their [✂]) alongside other hearing solutions such as CROS hearing aids, middle-ear surgery, and middle-ear implants.[30]

3.18 **Conclusion:** If the merged entity were to seek to increase prices or reduce the pace of innovation in the implantable bone conduction solutions segment, this would deter patients and health care professionals from switching away from other hearing solutions. Any such strategy would make no commercial sense

[27] See, for instance, Annex 022 – Target Bone Conduction Business Plan, page 5; Annex 011 – Acquirer 5-year Strategy FY22-26, page 19; Annex 010 – Acquirer Business Plan for Financial Years 2022-2026, pages 7, 9, 14, 24 and 29; Annex 109 – Acquirer Cross-Country Brand Tracker for US, Germany and China – 2021; Annex 015 – Acquirer Clinical Strategy 2021; Annex 221, pages 6 and 9; Annex 222, page 10; Annex 223, page 12; Annex 231, page 15; Annex 235, page 5; Annex 237, page 13; Annex 228; Annex 230, page 9.
[28] Annex 237, page 16.
[29] A recent study in the US suggests that 37% of the total population with some sort of hearing loss suffers from unilateral hearing loss in one ear and there is no reason to consider that this would be different in the UK. See Many Americans live with single-sided deafness | hear-it.org.
[30] See, for instance, Annex 226, page 5; Annex 227, page 6; Annex 234, page 17; Annex 221, page 6; Annex 222, page 10; Annex 224, pages 8; and Annex 220, pages 31 to 34.

given the countervailing buyer power of the public health systems, and the pace of innovation in the sector that is driven by technological innovations by the large hearing aid manufacturers and the sheer size of the opportunity to grow demand for hearing implants (that is in turn predicated on the need to build confidence and win over patients and HCPs through a sterling reputation for quality and reliability of products that are demonstrably superior to alternatives).

F. Closeness of competition – the Target is a diminishing competitor in bone conduction implants

3.19 Even if the Seller had not already decided to exit the market, there would be no realistic prospect of the Transaction hindering the maintenance of effective competition for the following reasons specific to the bone conduction solutions segment.

3.20 The Target has been a competitor in so-called passive percutaneous systems that have the disadvantage of a titanium post (an abutment) attached to the implant that juts out through the skin onto which a sound processor is connected. Passive systems result in a perpetual open wound that can require patients to be treated regularly in hospital due to complications in the form of infections, skin revision procedures, changes in abutment, and risks of implant loss. They also have significant disadvantages from an aesthetics and usability perspective requiring, for example, daily cleaning. They are also less suitable for children as the risk of explantation or moving the implant and abutment is significant. Passive systems are a first-generation technology that are likely to be redundant in the foreseeable future.

3.21 The Acquirer was first on the market with a passive system and maintained a strong market share after the Target entered. The Target's abutment is pure titanium whereas the Acquirer's abutment is coated with DermaLock™ Technology which helps the soft tissue to integrate with the implant resulting in improved healing of wounds and better osseoinetgration. The Target has, generally speaking, failed to innovate in respect of implants technology given that the focus of the core Seller business is non-implantable hearing aids.

3.22 The fact that the Target's sound processor offered compatibility with the Acquirer's abutment helped it to initially capture market share. As the pandemic hit, the Target was already losing market share in passive bone conduction solutions, not least due to the success of the Acquirer's Baha 6 Max sound processor that was launched in March 2021. The Baha 6 Max is the first bone conduction solution sound processor that allows for direct streaming from Apple and Android devices whereas the latest Ponto model only streams to Apple (Apple's IOS global market share is roughly 28% compared to Android's 70%).

3.23 The continuation of the Target's business based on the sale of passive bone conduction systems alone is not sustainable as the result of: (i) demand that is expected to continue to sharply decline in the near term, (ii) fixed common costs with the CI business would no longer be spread over the two businesses and would have to be recovered by the passive bone conduction business in its entirety, and (iii) the fact that the current profitability of the passive segment is overstated due to cross-subsidisation within the broader Demant business that is not adequately accounted for in the Target's financial statements.

G. There is no "market" for passive bone conduction implants

3.24 The total number of passive implant units sold in the NHS year 2021 (April 2021 to March 2022) in the UK amounted to approximately 1,850 units. Given these volumes, and the fact that other hearing solutions are credible alternatives across the range of hearing impediment conditions, neither Party has any conceivable pricing power, as separate entities today, or combined in the future.

3.25 **The market is switching rapidly to active bone conduction implants.** Coming out of the Covid-19 pandemic, active systems are growing rapidly relative to passive solutions, not least because active solutions do not involve an open wound nor an abutment which also has clear aesthetic advantages. The fact that so far active systems have a coverage of up to 55dB whereas superpower passive systems go to 65dB does not mean that passive implants have a long-term future. The Acquirer estimates that

approximately 5% of suitable patients with conductive or mixed hearing loss fall within the 55-65dB range. For this very small patient group, there are alternatives: reconstructive surgery; middle ear implants that go to 75-80dB; and hearing aids. It is also likely that in the near future active solutions will have a fitting range that matches passive solutions, [✂]. There is not one device that is suited to one type of patient with a given level of hearing loss. There is a large degree of overlap, and patients do transition over their lifetime given their particular needs and circumstances. There are no patients for which passive bone conduction implants are the only solution. Given this, and that both passive and active surgeries can be conducted under local anaesthetic (see paragraph 3.30 below), there will not be a need for passive bone conduction solutions in the foreseeable future.

3.26 **The Acquirer's own data on its Osia sales is indicative of the global switch to active systems.** Osia was launched in December 2019. By December 2022, sales of Osia passed the [✂]units tally, which makes it the fastest growing hearing implant system due to its increased fitting range and enhanced ease of surgery. Osia is the first osseointegrated steady-state design without moving parts due to the piezoelectric transducer that expands and contracts to create powerful vibrations that are sent through the skull bones to the inner ear. Osia has output to 55dB and there are indications of further gains at high frequency.

3.27 Osia sales already represent more than [✂] of all implants sold by the Acquirer in the US (even though the paediatric version of the product that serves the largest segment of demand will only be approved in [✂]), and in Latin America, that number is already at [✂].

3.28 Because post-pandemic healthcare systems are under such pressure across the board, acoustic surgery has been deprioritised and precious operating slots will increasingly be earmarked for active solutions.

3.29 This phenomenon is clearly observable in the UK where Osia was first launched in the region: the Acquirer has seen significant growth of Osia sales in the past 18 months in a manner which has cut [✂] into the Acquirer's sales of its passive products. The active implant share of the Acquirer's total bone conduction solution implant sales increased since its active Osia product was launched from [✂] in H2 2021, to [✂] in H1 2022, and to [✂] in H2 2022.[31]

	Apr – June 2021	**July – Sept 2021**	**Oct – Dec 2021**	**Jan to Mar 2022**	**Apr to June 2022**	**July – Sept 2022**	**Oct to Dec 2022**
Acquirer – sales of Baha implants (passive)	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]
Acquirer – sales of Osia implants (active)	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]
Active % of total Acquirer bone conduction implant sales	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]

3.30 This rapid take up of active solutions in the UK is occurring notwithstanding ongoing elective backlogs and industrial action in the UK, which have meant that not all clinics have yet switched to active solutions. Given those very constraints, one hospital (Manchester) has recently obtained approval to perform active bone conduction implant surgery in an outpatient setting. This means that the process can be likened to dental surgery in terms of the resources needed, freeing up surgical theatre staffing and precious hospital resources in a procedure that is done under local anaesthetic in less than 30

[31] Please refer to Annex 242 for a monthly breakdown of passive and active sales in the UK since the launch of Osia.

minutes and allowing the patient to return home after just a few hours. Since the community of specialist ENT surgeons carrying out hearing implants is small and well-connected, this development is expected to be followed by the other clinics quite quickly.

3.31 The Target's internal document relied on by the CMA[32] to conclude that there will still be a place for passive solutions for the foreseeable future given that treatment can be done under local anaesthesia and can provide better outcomes for lower treatment costs has been overtaken by events. Surgery for active solutions can be done using local anaesthesia and in a similar timeframe as passive solutions. Surgeons trained to perform passive implants can readily switch to perform active implants. Active implants can be done in an outpatient environment. A recent study by the Hearing Implant Team at Guy's and St Thomas' NHS Foundation Trust conducted a longitudinal economic analysis of a Med-El Bonebridge active solution against a percutaneous bone conduction solution over a five-year period and found that while the mean total cost per patient of Bonebridge was significantly higher than a passive bone conduction solution product at one year post-implantation, this difference was "*no longer statistically significant*" by five years post-implantation given the "*increased long-term complications, revision surgery rates and higher cost of the [passive bone conduction solution] processor compared to Bonebridge*". The study concluded that the long-term costs of Bonebridge to healthcare providers were comparable to passive bone conduction solutions "*whilst offering lower complication rates, comparable audiological benefit and patient satisfication*" and that "*Bonebridge should be considered as a first-line [bone conduction implant] option in appropriate cases*".[33]

3.32 All of this means that more clinics will supply active bone conduction solutions in the short term (as awareness and clinical evidence grow) and that there will be no need for passive bone conduction solutions in the foreseeable future. Indeed, a number of leading UK hospitals and clinics have already announced that they have switched entirely, or almost entirely, away from passive to active systems, as per the below charts.[34]

[✂] [✂] [✂][✂]

3.33 In the rest of Europe, the trends observed in the more advanced UK market are expected to accelerate once reimbursement is granted and training of clinicians ramps up. Patients are already demanding active solutions and surgeons are keen to transition even in markets where there is no agreed reimbursed price as yet. All of this means that the global market for passive bone conduction implants is shrinking. In developing economies that cannot support the extra cost of active implants, the default is likely to remain primarily hearing aids because of the lack of infrastructure to provide the additional patient support required as a result of the wound treatment complications associated with the passive abutment.

H. Med-El is a significant competitive constraint

3.34 The clear switch from passive to active contradicts the suggestion at in the CMA's phase 1 decision[35] that Med-El is a weak constraint given its focus on active bone conduction solution and its lack of a passive solution, it should be understood that Med-El has no passive system (and is not interested in the Target's technology) because the future is in active. No other modern medical device entails a metal abutment extruding from the body and a related permanent wound. The Parties therefore disagree with the CMA's conclusion[36] that it does not believe that the evidence indicates that Med-El would impose a strong competitive constraint on the Merged Entity in the foreseeable future. The Parties note:

(a) **Med-El was first to introduce such an active system ("Bonebridge") in 2012 and is a**

[32] CMA phase 1 decision, paragraph 112.
[33] Annex 380 – Longitudinal economic analysis of Bonebridge 601 versus percutaneous bone-anchored hearing devices over a 5-year follow-up period.pdf.
[34] Please refer to Annex 242 for the underlying data for these clinics.
[35] Paragraph 124.
[36] CMA phase 1 decision, paragraph 125.

significant competitive constraint. Med-El is a private company with a broad product portfolio and an established track record of significant innovation. Uptake of its pioneering first-generation product was slow as surgeons needed to be trained and gain confidence in the new technology, and many were uncomfortable with the depth of excavation in the skull required by the structure of the first-generation product. Med-El addressed this technical issue and reduced the depth by 50% with the introduction of a second-generation product (BCI 602) in 2019 shortly before the Covid-19 pandemic. Med-El introduced a new sound processor, SAMBA 2, for bone conduction and middle-ear implants in 2020. It has improved surgical handling and reduced operating times.

(b) Med-El's relatively low penetration of the overall bone conduction segment reflects the decline in hearing implant surgeries during the pandemic and the lag time in gaining traction from the introduction of the first-generation product. The second-generation product is the closest competitive constraint on the Acquirer as surgeries pick up and the market shifts rapidly to active systems as described below. The Acquirer expects that Med-El is currently working on a third-generation product with a broader fitting range to compete more directly with the Acquirer's Osia system.

(c) The Parties note that in its CMA phase 1 decision at paragraph 126, the CMA relies on the fact that Med-El's Bonebridge product is not "*directly comparable to that of the Parties' current and pipeline products*" to conclude that Med-El does not pose a competitive constraint. The Parties disagree with this given that Med-El Bonebridge product has [✂] over the Acquirer's active implant product ([✂]), and is expected to have [✂] over the theoretical Sentio product. In any event, if the CMA were to rely on Bonebridge not being directly comparable to Osia as a factor indicating that Med-El is not a constraint on the Acquirer, it would have to apply the same reasoning to Sentio which is expected to be [✂] and, ultimately, the Seller will not bring Sentio to market.

(d) The fact that Med-El's Bonebridge product has [✂] is reflected in the [✂] which track Bonebridge and Med-El. Please see, for instance:

(i) Annex 231 relating to a [✂] "*[i]n relation to our direct competitors in the transcutaneous active BC systems segment, Medel today offers a BoneBridge system that is* [✂]";

(ii) Annex 235 relating to a [✂]noting "*[w]ithin the acoustic implant segment, Medel has their Samba 2 Sound processor. It is* [✂]";

(iii) Annex 237 relating to relating to a [✂]:

(A) "*Expectation is that the Bonebridge system from Medel will be the main direct competitor.* [✂]"; and

(B) "*In relation to our direct competitors in the transcutaneous active BC systems segment, Medel today offers a BoneBridge system that is* [✂] *is to take next step even* [✂]";

(iv) Annexes 216 and 218 to 220 for examples of the Acquirer benchmarking its Osia product against Med-El Bonebridge (amongst other products); and

(v) Annex 224, an Acquirer board presentation on its acoustic business which notes at slide 8 Med-El "*active & non-surgical strategy*", pointing to in particular its [✂]. By way of comparison, the same slide in respect of the Target notes that it is following a [✂]; and

(vi) According to an Acquirer user survey conducted in February 2022,[37] [✂] of respondents [✂] Med-El's Samba (sound processor for Bonebridge) [✂] any of the [✂], and Samba scored [✂] than any of the [✂].

(e) As noted, Med-El is active across a broad spectrum of hearing solutions. Middle-ear implants in particular – in which neither Party is active – are a strong competitive constraint on bone conduction solutions in that they can also be used to treat sensorineural, conductive and mixed hearing loss and have a significantly broader fitting range compared to active and passive bone conduction solutions (Med-El's Soundbridge product has a fitting range up to 75-80dB). In addition, Med-El's ADHEAR non-surgical product is a "new to world" sound processing unit that sits on a small adhesive pad on the soft tissue behind the ear.

I. The Target is not a competitive constraint

3.35 **Despite the Target's significant efforts to develop an active bone conduction solution, it does not have a current offering nor a proven proof of concept**. The Target has been developing an active solution, Sentio, that was expected to launch globally in [✂], but this has been repeatedly [✂]. It has yet to be fully tested and to receive regulatory approval and, even if released [✂]. In addition, the Target is likely to face reimbursement challenges, particularly as the product (if released) is [✂].

3.36 While the Target at some point intended to launch the Sentio product for calendar year [✂], these plans have been shelved as the Seller is not prepared to make the lifelong commitment to support future potential patients of an active bone conduction solution which means that Sentio is essentially a stranded asset.

3.37 The Acquirer's Osia product was development for over a decade, driven mainly by Med-El's pioneering Bonebridge product, and before the Seller entered the hearing implants segment with a passive percutaneous bone conduction solution in 2009. The technological lead that Osia represents means that the Sentio product is not impacting the Acquirer's innovation incentives and is also a factor likely to dissuade any potential market entrant from acquiring the Sentio product that is still in development.

3.38 In its phase 1 decision, the CMA considers that there is "*strong evidence from Cochlear's internal documents to suggest that it considers Oticon Medical's active BCS product as a threat, given the extensive monitoring of its product specifications in comparison to Cochlear's own active BCS product*." The Acquirer notes that such monitoring of a potential product does not in itself provide an indication that the product, if launched, would constrain the Acquirer. Further, this highlights the inconsistency in the CMA's approach when reviewing such documents given that the Acquirer monitors products across the range of hearing solutions (including non-surgical, such as [✂], hearing aids and middle-ear implants) without the CMA concluding that those solutions constrained the Acquirer. Further, the Acquirer considers that such internal documents that evaluated the Target's Sentio product were based on assumptions and estimates rather than concrete knowledge[38] and that more recent documents reflect that that Acquirer does not consider Sentio to be a threat. For example, an Acquirer strategic product brief relating to [✂] [39] notes that [✂] are the main direct and indirect competitors in the section on "Competitive Market Access Environment" (while making no reference to Sentio), and a later section on "Competitive Marketing Environment" refers to the competition posed by "doing nothing", middle ear surgery, [✂] and notes that "[✂]".

3.39 For the avoidance of doubt, the Seller will not bring Sentio to market. This would have required the Seller to maintain relevant know-how and its Class 3 approved manufacturing site in Nice which would

[37] Annex 104 – Acquirer Perception Study – Jussi Market Research Launch – 25 February 2022, slide 3.
[38] See, for example, Annex 225 from May 2019 which compares Osia with Bonebridge and Sentio at pages 4 and 5, but is clear that much is unknown about Sentio, or Annex 231 from November 2021 which notes that [✂]. *Just like the BoneBridge from Medel, it includes an electromagnetic transducer. The SP and implant form factors are believed to be equal to the Medel BoneBridge*".
[39] Annex 237.

[✂] reduce the gross margin of the Target's bone conduction business. More fundamentally, it is not prepared to make the lifelong commitment to support future potential patients.

4. Drivers of Innovation

4.1 The Acquirer has a global innovation network with over 500 R&D employees across the globe and participates in over 100 collaborative research and sustainability programs worldwide. It communicates publicly that it is dedicated to build a market-leading portfolio of products and services that supports a lifetime of hearing outcomes for recipients. The Acquirer has consistently focused on R&D, with a public target of spending 12% of global revenue on R&D annually and spending 13% of global revenue on R&D in its most recent financial year. It has achieved a reputation for reliability and quality through a multi-decade philosophy of investing to grow and an unwavering commitment to innovation. Its 2022 Annual Report lists[40] as its business priorities to:

(a) "Maintain market leadership through growing levels of investment in R&D";

(b) "Innovation focus on hearing implants, sound processing technology, connectivity and clinical and surgical support"; and

(c) "Introduce new products that provide improved hearing outcomes, functionality, connectivity and aesthetic benefits".

4.2 Innovation will continue to be driven by the commercial incentive to expand the hearing implants segment, increase penetration amongst eligible patients and continue to provide existing patients with improved products and services and the need for the merged entity to compete against patient inertia and unawareness, reconstructive surgery, and other manufacturers of hearing implants (Med-El and Advanced Bionics) and other hearing solutions. The Acquirer has every incentive to remain at the cutting edge of innovation to profit from providing existing patients with improved sound processors and accessories, to keep pace with other hearing technologies (especially hearing aids), and because of the need to demonstrate significant qualitative innovations if national health services are to be persuaded to pay for them.

4.3 The Acquirer has been a leader in providing continual service support that is increasingly seen as a driver of brand choice including warranties, repair and replacement time, access to troubleshooting, rehab tools, and education.

4.4 The ability of both patients and HCPs to use tools to effectively manage patients remotely is increasingly a brand differentiator, particularly given the recent impact of COVID. This ensures that patients do not have to travel to engage with their HCP and ensures continuing care in a meaningful way. As noted at paragraphs 3.9(e) and 3.9(f), innovation in this space (and the Acquirer's monitoring of activities in this space) is led by hearing aid manufacturers.

4.5 All players have been improving connectivity, introducing the ability to stream directly to their products from a device (e.g., a smartphone) and to open up the ability for patients to schedule remote appointments. The Acquirer has a "Connected Care" package helping HCPs deliver the best possible outcomes for their patients through tailored offerings targeting Surgical Care, In-clinic Care, Remote Care and Self-managed Care. Similarly, Med-El has a DirectCare service – a troubleshooting service through which patients can contact Med-El directly without going to hospital – which a patient survey indicated was [✂] and [✂].

4.6 In view of all the above innovation and sustainability endeavours carried out by the Acquirer historically (and the ones already planned for the future), it is only reasonable to conclude that these efforts are

[40] https://mss-p-007-delivery.sitecorecontenthub.cloud/api/public/content/e8ef753515b44ae8bd0dee91541dcdb6?v=92e56b8e, pages 29 and 76.

independent of the Target's theoretical competitive pressure. The Target is not an innovator and has at best been a follower that has failed to keep up with the most recent technological innovations. The Target is concerned to ensure that the Target's installed base is cared for to avoid setting back its decades long efforts to build confidence in and expand the hearing implants segment. The Transaction would provide the Acquirer with greater scale and would enable the company to increase investments in R&D and market growth activities. Innovation will continue to define the Acquirer's presence in the market as it is at the heart of the Acquirer's success.

4.7 As explained by the Seller at the Site Visit in January 2023, innovation in this segment is also fundamentally driven by patients' needs and the medical research community, including key opinion leaders ("**KOLs**"). Researchers and the medical community, including KOLs, will continue to push for innovation in the medical implants segment as it is required for patients' treatment. A failure to provide such innovation post-Transaction risks patients switching to only available solutions, as describe in paragraph 3.18 above, and would be an irrational commercial decision that would only further shrink the already small bone conduction solutions segment.

5. Countervailing Buyer Power

5.1 The very significant majority of bone conduction implant sales ([✂]%) is via the NHS that has substantial purchasing power.

5.2 In its phase 1 decision,[41] the CMA did not consider that buyer power would be sufficient to mitigate an SLC in bone conduction solution, given "*there will be a lack of an effective alternative supplier available to the NHS and/or clinics post-Merger*". This conclusion does not account for the role of Med-El in bone conduction solutions. It also does not account for the constraint posed by other effective hearing solutions, including hearing aids, reconstructive surgery, middle-ear implants all of which are well-established alternative acoustic therapies. There is no patient for which a bone conduction solution provided by the merged entity would be their only option, so the NHS will always have effective alternatives. If for certain patients bone conduction solutions were truly their only option, we would expect to see the level of penetration materially exceed 2%. These alternatives, coupled with the very small volumes of bone conduction implant products concerned, mean that the merged entity will enjoy no market power whatsoever.

5.3 Hospitals and practitioners have no significant costs from switching between suppliers of bone conduction solutions, or to other hearing technologies.[42] Physicians are typically trained to use implants from different suppliers interchangeably. Suppliers train the medical personnel at the hospital to use their products free of charge. Patients rarely change the implant they have, since it would require undergoing a new surgery to remove the implanted device and replacing it with another one which means manufacturers compete fiercely to be the chosen implant supplier.

5.4 Given this, clinics can use the very credible threat of switching to well-established suppliers of hearing implants or to other hearing solutions and would do so in the event that the merged entity sought to increase prices, lower quality, or decrease its innovation efforts.

5.5 This availability of other options and the small role played by bone conduction solutions undoubtedly has an impact on the ability of bone conduction solution suppliers to raise prices or reduce innovation when bidding for the entrance into national framework agreements. Prices for bone conduction solutions are determined and negotiated between the supplier and NHS Supply Chain, with a Devices Working Group (a group of professionals with direct experience of bone conduction solutions, including NHS

[41] CMA phase 1 decision, paragraph 179.

[42] When a patient is recommended a hearing implant after a wider consideration of the clear effective alternatives, it is usually the ENT (ears, nose and throat) team in the hospital or clinic that decides based on price, the product's characteristics, and especially on the service provided by the supplier. Patients are normally guided to pick the device recommended by the ENT team as the most appropriate for the patient. In the vast majority of cases, patients accept the medical practitioner's recommendation.

England personnel) evaluating products and proposed prices/terms. The Working Group authorises the addition of new products to the framework and has the option to decline a new product if the cost outweighs the perceived benefit vis-à-vis existing products on the framework. There is a real need on bone conduction solution suppliers to demonstrate benefits in terms of technology, innovation and price – particularly given the prevalence of other options – otherwise there is a risk that will not be selected for a particular framework. The NHS exercises a constant downward pressure on prices, with average selling prices declining by 1% to 2% per year, despite new technology being launched. The CMA in its phase 1 decision considered that it had not seen any evidence or examples of the NHS negotiating against any price increases with regards to bone conduction solutions.[43] As noted to the CMA, the Parties have never tried to gain a higher price for existing products on the market and, given this, no such evidence or examples exist. This is evidence of buyer power in action. The Acquirer strives to work in partnership with the NHS to improve patient care. Even for new innovative products (such as Osia), suppliers are only able to seek nominal price increases (relative to the price for old/existing products) if they are able to demonstrate and quantify the increased value that the new product will provide to the patient/NHS (such as through the submission of detailed and evidenced-led value dossiers).

5.6 Further, at clinic level, clinics in the UK operate under a visible cost model for bone conduction solution products, where clinics have visibility of the cost of products and price would be a factor taken into account. This was a shift from the previous zero-cost model where clinics did not see the price of bone conduction solution products and made decisions solely based on the clinical outcome. Under the "Clinical Commissioning Policy: Bone conducting hearing implants (BCHIs) for hearing loss (all ages)" guidance used by NHS England and generally followed by Wales, Northern Ireland and Scotland, where a candidate is suitable for more than one bone conduction solution product the most cost-effective option must be selected by the clinician with patient involvement.

5.7 In addition, the Parties note that the NHS contracts and procurement guidelines themselves impose power and pressure on the Parties, insofar as they generally prohibit any increases in price during the contract term, impose obligations on suppliers to identify cost savings, and require suppliers to provide justification for any price increase at contract renewal.[44]

5.8 The lack of education focused on hearing implants and patient referral pathways in the UK often mean that patients who would best be treated by a hearing implant do not consider or are not made aware of it as an option recommended by HCPs. The fact that pathways are designed with hearing aids in mind first is reflected in the fact that the NHS England commissioning policy notes that (i) the preferred method of rehabilitating hearing loss is to use conventional hearing aids and (ii) patients must trial a conventional hearing aid or a wireless CROS hearing aid for a minimum of 4 weeks, or a non-surgical solution for a minimum of 14 days, before a surgical bone conduction solution product is even considered.[45] This, combined with patient inertia and reluctance and the minimal education regarding hearing implants, naturally has an impact on patients and HCPs considering bone conduction solutions products as an option. Unlike hearing aids, hearing implants are lifelong products so HCPs are reluctant to recommend to patients unless they are convinced and certain of the added value or benefits. Given their lack of focused education on such benefits, or on the surgery itself, many HCPs may feel unable to recommend in this way.

5.9 The threat of the NHS switching even a small number of bone conduction units to Med-El or to alternative therapies would have an immediate detrimental impact on the business. The merged entity is effectively beholden to the public healthcare systems and significantly constrained in terms of having to maintain low prices, maintain high product quality, and invest in the need to innovate to a level that is a demonstrable improvement over existing technologies in order to be reimbursed. With the NHS

[43] CMA phase 1 decision, paragraph 180.
[44] See Annex 238, Schedule 6; Annex 239; Annex 240, Section 8; and Annex 241, Clauses 15 and 16.
[45] https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2013/05/16041_FINAL.pdf.

comprising over [✂]% of the merged entity's sales of bone conduction systems (by volume and value), the Acquirer will have no option than to continue to partner with the NHS in delivering a value for money demonstrably better solution for patients; the NHS, on the other hand, has many options in respect of other hearing implants and other hearing solutions.

6. Entry as a Countervailing Factor

6.1 If the segment grows, or if the merged entity were to attempt to raise prices or decrease its innovation efforts, new competitors may be likely to launch competing bone conduction solutions. For example:

(a) Medtronic also has an abutment-free passive transcutaneous bone conduction implant product in the US (Alpha 2 MPO eplus) compatible with 3 Tesla MRI scans, high dB output (121 dB), and long-lasting battery life of up to one year. Such premium products may be rolled out globally.

(b) Envoy Medical has incorporated a German entity (Envoy Medical GmbH) and registered the domain name "envoymedical.eu", a website which also points to "further information" regarding its Esteem middle-ear implant product.

(c) BHM Tech (an Austrian company) is another company active in non-surgical bone conduction solutions with its "Contact Forte" and "Contact Mini" products. It is understood that its "Forte" product was launched in December 2020.

(d) Finally, the big tech companies, especially Apple, Samsung and Google, are also investing heavily in health and are already active in the hearing space. They could potentially quickly disrupt the market using their own technologies in the hearing loss space.

6.2 Given the anticipated growth of the implantables segment, and notwithstanding the regulatory barriers and concerns of HCPs around long-term reliability, potential entry by those able to provide innovative or high-quality solutions must be viewed as likely.

7. Relevant Customer/Public Health Benefits

7.1 As set out in the CMA's Merger Assessment Guidelines, the CMA may take into account the relevant customer benefits of a merger, including lower prices, higher quality, greater choice or greater innovation in relation to goods or services.[46]

7.2 In light of the Seller's decision to discontinue its hearing implants business, absent the Transaction the Seller will close its cochlear implants business, discontinue activities within bone conduction solutions, and will [✂]. The Target's patients would not therefore [✂]. There would be [✂]. For cochlear implant patients in particular, their ability to communicate and their quality of life would be [✂].They would likely have to [✂]. In addition to the non-quantifiable costs [✂], the [✂] would have significant direct costs to the national health systems (in terms of both unwelcome costs and the diversion of scarce resources).

7.3 This is the rationale for the Acquirer entering into the Transaction which manifests differently with respect to cochlear implants and bone conduction solutions:[47]

(a) **Goal No. 1: Prevent harm to the reputation of cochlear implants** – In the absence of the Transaction, the Seller would close its cochlear implant business and supply only [✂]. The Target's cochlear implant patient base would therefore [✂]. While the Target would be able to continue repairs in the short-term, [✂]. For such cochlear implant patients, they would have to

[46] CMA Merger Assessment Guidelines, paragraph 8.21.
[47] The CMA noted in its phase 1 decision at paragraph 25 that the Acquirer's internal documents broadly support this strategic rationale.

have their implants [✂].

The Acquirer is committed, and has committed publicly, to providing long-term support to these patients, including by adapting its sound processor technology to provide ongoing support to the approximately [✂] patients globally that have received the Target's cochlear implants. The Acquirer can breakeven supporting these patients, and the credibility of the Acquirer and the industry is likely to be enhanced in the eyes of professionals as a result. The Acquirer has a track record in protecting orphaned patients and in developing cross-compatible technology. The potential for the Target's patient base to be stranded as outlined above would hurt industry reputation and the willingness of patients to opt for hearing implants as a therapy option. Hearing implants are by their nature designed to be a lifetime solution, and HCPs may be more reluctant to recommend, or patients may be deterred from opting for, hearing implants as a therapy if they feel that there is no guarantee of continuity or lifetime support from hearing implant manufacturers. This would be an industry-wide impact which the Acquirer is determined to avoid.

(b) **Goal No. 2: Increase investment in bone conduction solutions** – Bone conduction solutions represent a very small therapy area in the treatment of mixed, single-sided and conductive hearing loss where the predominant treatments are standard hearing aids, CROS hearing aids, reconstructive middle-ear surgery, and middle-ear implants. Market research has indicated that patients and HCPs have low awareness and familiarity with bone conduction solutions. In order to grow the bone conduction solutions segment to compete with these alternative treatments, scale is needed to invest in advancing the technology and in increasing knowledge and confidence in the products on the part of HCPs. The Transaction will (i) give the Acquirer access to a larger installed patient base that will facilitate the development of clinical evidence to better demonstrate the effectiveness of these products (in particular versus hearing aids), and (ii) free-up resources by avoiding the duplication of efforts in gathering clinical evidence and in ensuring compliance in an increasingly complex and expensive regulatory environment. These efforts are vital to improving patient access.

7.4 It is clear that the benefits to the Target's installed base of patients – both in terms of support, access to upgrades and features, and access to innovative products – outweighs the impact of the Transaction and are significant compared to the scenario of the Seller exiting the business and providing [✂] maintenance in the short-term. There is therefore an important public interest element that supports rapid approval of the Transaction so that the R&D and engineering required to ensure the Target's installed patient base is adequately supported can begin.