

## MAGEC timeline

<b>Date</b>	<b>Summary</b>	<b>Link to published documents</b>
27/06/2019	2019/006/027/487/006 FSN	<a href="#">Medicines and Healthcare products Regulatory Agency (filecamp.com)</a>
18/02/2020	2020/002/018/291/002 FSN	<a href="#">Medicines and Healthcare products Regulatory Agency (filecamp.com)</a>
03/03/2020	MHRA email request for voluntary suspension	
18/03/2020	MDA/2020/010 MDA	<a href="#">Spinal implant: MAGEC System Model X rods – risk of failure in use (MDA/2020/010) - GOV.UK (www.gov.uk)</a>
March – Sept 2020	MHRA 6-month investigation into the safety and performance of the MAGEC system and review of the effectiveness of the manufacturer's Quality Management System. A full technical file review and external stakeholder engagement.	
01/04/2020	MDA/2020/011 MDA	<a href="#">Spinal implant: All MAGEC Systems – supply suspended to the UK (MDA/2020/011) - GOV.UK (www.gov.uk)</a>
01/04/2020	2020/003/010/479/001 FSN	<a href="#">Medicines and Healthcare products Regulatory Agency (filecamp.com)</a>
29/07/2020	Spinal Expert Advisory Group (SEAG) meeting	
26/08/2020	SEAG meeting	
14/09/2020	MHRA report to Notified Body DQS sent	
15/09/2020	SEAG meeting	
21/10/2020	SEAG meeting	
25/03/2020	The Notified Body, DQS Med, suspended the CE certification for the MAGEC [REDACTED] [REDACTED]	
31/03/2021	SEAG meeting	
05/04/2021	NuVasive Company Statement	<a href="#">Company statement MAGEC and Precice CE Mark 09April2021 FINAL (nuvasive.com)</a>
06/05/2021	Targeted letter issued by MHRA to inform UK of the CE certification suspension DSI/2021/007	<a href="#">Targeted communication: CE mark suspended for all MAGEC systems manufactured by NuVasive Specialized Orthopedics, Inc. (DSI/2021/007) - GOV.UK (www.gov.uk)</a>

24/11/2021	The MHRA were informed the CE certificate had been reinstated for MAGEC. The Instructions for Use (IFU) has been updated and NSO have issued a FSN.	
14/12/2021	2021/012/014/601/504 FSN	<a href="https://www.filecamp.com">Medicines and Healthcare products Regulatory Agency (filecamp.com)</a>
15/12/2021	SEAG meeting	
Jan 2022- June 2022	Review of the updated MAGEC technical file [REDACTED] [REDACTED] [REDACTED].	
04/2022	The 'modified' MAGEC X has gained a CE marking approval	
18/05/2022	SEAG meeting	
13/07/2022	SEAG meeting	
July to October 2022	Final Conditions discussed with SEAG via correspondence. Final condition letter sign off.	
17/10/2022	MHRA letter of conditions sent to NSO	
17/10/2022	NSO acknowledged MHRA letter of conditions	
14/11/2022	MHRA chase for update on NSOs position with the letter	
21/09/2023	MHRA: NSO Meeting regarding updates on the status of MAGEC [REDACTED] [REDACTED] [REDACTED]	
19/10/2023	NSOs written response to the condition letter dated 14/10/2022	
29/11/2023	MHRA email response to NSOs proposed amendments to the MAGEC conditions	
06/12/2023	MHRA internal Signal Management Review Meeting – Assessment of NSOs response and proposals	

06/12/2023	NSO response to MHRA email of the 29/11/2023	
13/12/2023	MHRA request to NSO for further information.	
30/01/2024	Meeting with NSO via Teams to discuss MHRAs proposed changes to conditions. MHRA updated conditions shared with NSO.	
06/02/2024	Final condition letter sent to BRE II Deputy Director	
07/02/2024	NSO confirmed informally that they were happy with the proposed changes to the conditions discussed in the meeting on the 30/01/2024	
09/02/2024	Final condition letter cleared by BRE II Deputy Director Final condition letter sent to MHRA CSO	
16/02/2024	Final condition letter cleared by MHRA CSO	
20/02/2024	MHRA letter to NSO detailing updated conditions	
23/02/2024	NSO agreed conditions proposed by MHRA in	
27/02/2024	Post publication note added to MDA and DSI	
07/03/2024	NSO distributed FSN	
11/03/2024	MHRA published NSO FSN on MHRA website	<a href="https://mhra.gov.filecamp.com/s/d/QJC7iWyianTs35zs">https://mhra.gov.filecamp.com/s/d/QJC7iWyianTs35zs</a>
12/03/2024	MHRA DSI published DSI/2024/002	<a href="https://www.gov.uk/drug-device-alerts/magec-x-system-nuvasive-specialized-orthopedics-nso-uk-suspension-lifted-dsi-slash-2024-slash-002">https://www.gov.uk/drug-device-alerts/magec-x-system-nuvasive-specialized-orthopedics-nso-uk-suspension-lifted-dsi-slash-2024-slash-002</a>
13/02/2024	MHRA DSI distribution to stakeholders	