Display/View\Correspondence

AITS Incident No: [redacted] Investigation level = Trending & Surveillance

Summary

Incident Number	[redacted]		
Report Type	Incident	Reported as Vigilance	Yes
Initial Review of FSN by TMG?	No		
Reporting Organisation	B. Braun Surgical, S.A.	Action	Trending & Surveillance
		Action Changed on:	
		Reason Action changed:	
Injury	None	Current Status of Investigation	
Serious Public Health Threat?	No	Manufacturer	B. Braun Surgical, S.A.
Incident Classification	All other reportable incidents	Report Type	Final (Non-reportable incident)
FDA?	No	Reporter has sent to the following	
RO is investigating?	No	Location of Incident / Name of Healthcare Facility	[redacted]
		Country of Occurrence	England
Is this a report of multiple events?	No		
Periodic Summary Report (PSR) ID			
Responsible Officer	A DSS RO	Field Actions	do we need this anymore?
Last 3 Monthly Review		Next Review Due on	
Clinical Investigation			
		Do not show for On Holds	
If the incident occurred within a PMCF/ PMPF investigation; please provide the Eudamed ID of that PMCF/ PMPF investigation			

Echo
Incidents
Known
Incidents
Similar
Incidents
If this incident involves multiple devices from the same manufacturer, please list the respective reference numbers of the other MIR forms you have submitted
NCA's Local reference Number
EUDAMED reference number
Manufacturer's reference number
If this incident is covered under an FSCA, please provide the relevant numbers:
NCA's FSCA reference Number
EUDAMED's FSCA reference number
Manufacturer's FSCA reference number

You will be able to import a list of incident numbers that this signal report refers to.
If you change the incident type from Signal Report to something else then this field will be automatically emptied (might do that overnight OR just hide the field if type is not Signal Report)
Buttons only visible or

	Signals
Eudamed	AIM File
Number of NCA Reference Number assigned by EUDAMED for this incident	

Origin

Reporting Route	MORE	Acknowledgement Required	No
Xmlversion			
REPORTER DETAILS:		ALTERNATIVE CONTACT DETAILS:	
Reporter Name		Alternative Contact Name	
Position/Occupation		Position/Occupation	
Reporting Organisation	B. Braun Surgical, S.A.	Alternative Contact Details Facility Name	
Address	N/A Carretera de Terrassa, 121 N/A	Address	
Town/City	Sheffield	N/A Carretera de Terrassa 121 N/A	
Postcode	S35 2PW		
Country	GB		
Telephone Number		Telephone Number	
Email Address	[redacted]@bbraun.com	Email address	
Email Copy To			
Local Reference Number			
Laboratory		Consultant in Charge	
Report Source	Role	Health/Social Care Organisation	StHA
	Manufacturer	Manufacturer	
Other Reporter Country	B. Braun Medical Ltd.		
Date Received	22/10/2021	Expected Date of Next Report	10/01/2022

Device: Core Information

Core Information | Additional Devices | Sample/Decontamination

BH Code	68/21	From User Report on web	
Device Description	Adhesive Control Devices	Product Name	
Item Description	Liquid skin adhesive/sealant	Product Category	Soft tissue implants
Model	HISTOACRYL	CE Mark	
Brand	HISTOACRYL BLUE TISSUE ADHESIVE 0.5ML	Device Class	MDD Class III
MDD/AIMDD	class III	IVDD	
MDR		MDR Type	implantables
IVDR		IVDR Type	implantables
Catalogue No.	1050052	ECRI Code	
Serial Number		Nomenclature System	GMDN

Batch Number / Lot Number	Unknown 219393N2	Nomenclature Code	58777
Software Version		Nomenclature text/ Description of the device and its intended use	Histoacryl is a sterile, liquid tissue adhesive consisting of n-butyl-2-cyanoacrylate. For easy visual assessment of the thickness of the layer which has been applied Histoacryl is coloured with D&C violet No. 2 dye. A colorless version, which does not contain dye, is also available. Histoacryl is supplied in 0.5 mL single use plastic ampoules. One ampoule should only be used in one patient. Each ampoule is sealed within an aluminium pouch in order to protect the ampoule from external contamination keeping at the same time the external sterility of the ampoule. Histoacryl remains liquid until exposed to water or water containing substances, including tissues. For easy assessment of the thickness of the layer which has been applied HistoacrylÂ® is coloured blue with the dye D&C violet No. 2. A translucent version, which does not contain dye, is also available. Histoacryl is indicated for: 1. SKIN CLOSURE: Closure of skin wounds without tension (including clean surgical incisions and incisions from minimally invasive surgery), and simple, thoroughly cleansed, trauma-induced lacerations. 2. SCLEROTHERAPY: Sclerotherapy of large oeÂ¬sophageal or fundal varices. 3. MESH FIXATION: Fixation of hernia meshes, especially in inguinal hernia surgery.
Firmware Version		If other, Please Specify the medical device Terminology	
Legislation Category		GMDN Code	
Date Manufactured		Notified Body Number1	0123
Date Supplied		Notified Body Number2	
Expiry Date		Notified Body Certificate Number 1	G7 18 02 25701 080
UDI Device Identifier/Eudamed ID	Unknown	Notified Body Certificate Number 2	
UDI Production Identifier	Unknown	Notified Body Name	
Basic UDI-DI/Eudamed ID	Unknown		

Unit of use UDI-DI			
Approximate Age of Device (FDA)		Number of Medical Devices involved	
Current location of Medical Device	Unknown	Device Accessories (FDA)	
Location of device, if other			
Name and Address of Reprocessor (FDA)			
Mfr Ref Number	[redacted]	Regulatory/ Competent Authority who approved device	
IVD Annex 2 Device	No	Other 3rd party name who approved device	
IVD Preservative		Document Approval Number	
IVD Accessory to Disease (IVD Only)			
Please indicate the date of one of the following	The device first CE marked		
If Software, date first made available	Year 2011 Month 12		
Default Adress for Letters	Manufacturer		
Manufacturer's Group Name	Braun and Company Limited	Supplier's Group Name	
Manufacturer	B. Braun Surgical, S.A.	Supplier	-
Manufacturer's Single Registration Number			
Manufacturer's Address	N/ACarretera de Terrassa,121N/A	Supplier's Address	
Manufacturer's Town/City	RubÃ	Supplier's Town/City	
Manufacturer's Postcode	08191	Supplier's Postcode	
Manufacturer's Country	ES	Supplier's Country	
Manufacturer Contact		Supplier Contact	
Manufacturer Phone No	[redacted]	Supplier Phone No.	
Manufacturer E-Mail	[redacted]@bbraun.com	Supplier E-Mail	
		Where did you get the device?	
		Other please specify	
Authorised Group Name			
Authorised Representative		Name of where you got device	
Authorised representative's Single Registration Number			
Authorised Address		Address	
Authorised Town/City		N/A	
Authorised Postcode			
Authorised Country			
Authorised Contact		Name of Person	
Authorised Phone		Phone	
Authorised Email		Can we send your personal details to the medical device manufacturer?	
NCP Group Name		Submitter Group Name	
NCP Name	B Braun Medical Ltd (UK) - Hypodermic needles etc,)	Submitter	B. Braun Surgical, S.A.
NCP Address	Thorncliffe Park	Submitter Address	N/A Carretera de Terrassa 121 N/A
NCP Town/City	Sheffield	SubmitterTown/City	RubÃ
NCP Postcode	S35 2PW	Submitter Postcode	08191
NCP Country	UK	Submitter Country	ES
NCP Contact	[redacted]	Submitter Contact	[redacted]

NCP Phone	[redacted]	Submitter Phone	[redacted]
NCP Email	[redacted]	Submitter Email	[redacted]@bbraun.com

	Time period 1:	Time period 2:	Time period 3:	Time period 4:
Start date				
End date				
Number of similar incidents:				
Country				
EU				
World				
Number of devices placed on the market:				
Country				
EU				
World				

Variant	Description
Device: Prosthetic	
Device: WMS	
Device: Orthopaedic	
Device: Pacemaker	
Device: Breast Implants	
Device: Haemostasis	
Device: Cochlear Implants	
Additional Devices	

	Associated Device 1	Associated Device 2	Associated Device 3	Associated Device 4
Mfr Name				
Other (mfr not found in list)				
Brand Name				
Model Code or No.				
Catalogue Code or No.				
Serial No.				
Batch No.				
Software Version				
CE Marked				
NB ID				
Mfr Tel No (for IVD Kit)				
Supplier (for IVD Kit)				
Supplier Tel No (for IVD Kit)				
BH/SE Code				
Relevant associated devices used with device being reported on (Please list with corresponding manufacturer if different from device being reported on)				
Relevant accessories used with device being reported on (Please list with corresponding manufacturer if different from device being reported on)				

Device: Sample/Decontamination

Date Received		Decontaminated by Reporter	
MHRA Sample Number		Method Used	
Quantity		Decontaminated by MHRA	
Location		Method Used	
Date Sent/Disposed		Photographed by MHRA	
Device Sent to Other		How sent	
MHRA to retain the device	No	Date to be retained until	

Attachment Point:

Sample/Decontamination Audit pre2010:

Incident

Date of Incident From	01/01/2019	Date of Incident To	14/10/2021	Reported as vigilance?	Yes
Reported Device Cause/ Effect					
Reported Actual Injury	None	Reported Clinical Effect	None	Potential Injury Potential Injury	Serious
Reported Actual Injury					
Type of Incident		Number of people injured / Number of patients involved	1	Event Problem Code (FDA) (Patient & Device)	
If Implanted Date From		If Explanted Date From		Implant Duration	Days Months Years
If Implanted Date To		If Explanted Date To			
Implant Facility Name		Explant Facility Name			

Incident/Failure Description:

The Coroner has informed us three additional cases at [redacted].
These additional cases are not deaths but events where details are not known.

Additional information has been requested.

This report is for second new case.

The MHRA reference numbers of the previous cases are: [redacted] (B. Braun Surgical ref. [redacted]) and [redacted] (B. Braun Surgical ref. [redacted])

Final (Non-reportable incident)
==========
The Coroner has informed us three additional cases at [redacted].
These additional cases are not deaths but events where details are not known.

Additional information has not been provided.

This report is for second new case. Manufacturer's reference numbers for the other two new cases are 400532237 (Reference assigned by MHRA: [redacted]) and [redacted] (MHRA reference: [redacted]).

The MHRA reference numbers of the previous cases are: [redacted] (B. Braun Surgical ref. [redacted]) and [redacted] (B. Braun Surgical ref. [redacted])

Was the patient a confirmed case of Covid19?
Was this defect confirmed with another device?
If so, please provide details of the confirming test:
Details of Injury(to patient, carer or healthcare professional)
Is this related to a Covid-19 diagnostic test?
Description of injuries/ treatments/ clinical effects:

Device Problem		1st level hidden		1st level	
Device Problem 1- (Level 1)	A26 - Insufficient Information	Device Problem 1- (Level 2)	-	Device Problem 1- (Level 3)	- MHRA Specific
Device Problem 2- (Level 1)		Device Problem 2- (Level 2)		Device Problem 2- (Level 3)	
Device Problem 3- (Level 1)		Device Problem 3- (Level 2)		Device Problem 3- (Level 3)	
Device Problem 4- (Level 1)		Device Problem 4- (Level 2)		Device Problem 4- (Level 3)	
Device Problem 5- (Level 1)		Device Problem 5- (Level 2)		Device Problem 5- (Level 3)	
Device Problem 6- (Level 1)		Device Problem 6- (Level 2)		Device Problem 6- (Level 3)	

If you think the incident is unique and a suitable IMDRF term is missing, briefly explain
Action taken by staff / manufacturer:
Manufacturer additional comments:

Health Effects Annex E

Clinical Signs,Symptoms and conditions 1 - (Level 1)	E24 - Others	Clinical Signs,Symptoms and conditions 1 - (Level 2)	E2401 - Insufficient Information	Clinical Signs,Symptoms and conditions 1 - (Level 3)	- MHRA Specific Clear MHRA Specific
Clinical Signs,Symptoms and conditions 2 - (Level 1)		Clinical Signs,Symptoms and conditions 2 - (Level 2)		Clinical Signs,Symptoms and conditions 2 - (Level 3)	
Clinical Signs,Symptoms and conditions 3 - (Level 1)		Clinical Signs,Symptoms and conditions 3 - (Level 2)		Clinical Signs,Symptoms and conditions 3 - (Level 3)	

Clinical Signs,Symptoms and conditions 4 - (Level 1)		Clinical Signs,Symptoms and conditions 4 - (Level 2)		Clinical Signs,Symptoms and conditions 4 - (Level 3)	
Clinical Signs,Symptoms and conditions 5 - (Level 1)		Clinical Signs,Symptoms and conditions 5 - (Level 2)		Clinical Signs,Symptoms and conditions 5 - (Level 3)	
Clinical Signs,Symptoms and conditions 6 - (Level 1)		Clinical Signs,Symptoms and conditions 6 - (Level 2)		Clinical Signs,Symptoms and conditions 6 - (Level 3)	
Health Effects Annex F					
Health Impact 1 - (Level 1)	F24 - Insufficient Information	Health Impact 1 - (Level 2)	-	Health Impact 1 - (Level 3)	- MHRA Specific Clear MHRA Specific
Health Impact 2 - (Level 1)		Health Impact 2 - (Level 2)		Health Impact 2 - (Level 3)	
Health Impact 3 - (Level 1)		Health Impact 3 - (Level 2)		Health Impact 3 - (Level 3)	
Health Impact 4 - (Level 1)		Health Impact 4 - (Level 2)		Health Impact 4 - (Level 3)	
Health Impact 5 - (Level 1)		Health Impact 5 - (Level 2)		Health Impact 5 - (Level 3)	
Health Impact 6 - (Level 1)		Health Impact 6 - (Level 2)		Health Impact 6 - (Level 3)	
If you think the incident is unique and a suitable IMDRF term is missing, briefly explain					
Usage of Device	Initial use	Is this a report of multiple incidents ?	Yes	Operator of Device at Time of the Event	Healthcare professional
Other Usage of Device				Other Operator of Device at Time of the Event	
Manufacturer Contacted	No	Manufacturer awareness date	15/10/2021		
Manufacturer aware of similar adverse incidents		Number of adverse event reports received by the manufacturer with the same root cause		Countries where similar events occurred	
Relevant Tests, Lab Data (FDA):					
Other Relevant History (FDA):					

FSCA

FSCARF / FSN Attached?	Neither
FSN Status	
FSCA reference number assigned by NCA	

Name of co-ordinating NCA and their incident reference
Advice on Actions to be taken by distributor and user
Progress of FSCA, together with reconciliation data
Attached

Time Schedule for the implementation of different actions
Background information and reason for the FSCA:
FSCA related attachments:
Description and justification of the Action (corrective/preventive):

Initial Reporter

Role of Initial Reporter	other
If other please specify	[redacted]
Name	
Healthcare Facility (user) report reference number	
Address	[redacted]
Town/City	
Postcode	
Country	GB
Email	
Phone	
Contact Name	
Job Title	
Date of Awareness or Date of Report (FDA)	

Legal

Litigation - hide for AITS4 hlr 042	No	Guarantee Claim - hide for AITS 4 HLR 42	No
Coroners Investigation	No	Police Investigation	No
		HSE Investigation	No
		Other Investigation	No
		create an attachment doc with suitable title & display in History view	

Patient

Patient Identifier (FDA)	
Date of Birth	
Age of patient at time of event	
Unit of Age	Years
	Months
	Days
Gender	Unknown
Weight in Kilograms	
List of Devices involved with each patient	
Patient-focused Resolution of Events and Outcomes	
Corrective action taken relevant to the care of the patient	
Patient Outcome	
List any of patient's prior health condition or medication that may be relevant to this incident	
Additional Details of Patient	

Trend

Date the trend was identified
Description narrative for identified trend
Time period of trend analysis
Established trigger level
Have any of the trended events been submitted individually as reportable events under vigilance ?
If Yes, please list how many and to which Competent Authority

PSR

PSR Type
If incidents described in a Field Safety Notice, Manufacturers reference number for FSN/FSCA
Stage of PSR reporting based on
Nature of problem agreed for PSR reporting
Summary period agreed
The figures in the table below relate to
Information for PSR summary period
Investigation update for this period

Signal Detail

Triage

Responsible Unit	DSS	Responsible Officer	A DSS RO
		RO Telephone Number	
Unit Manager	DSS PT	Date Allocated	28/10/2021
Team		Team Manager	
Data Input Complete	28/10/2021	Select Alternative Initial Letter to be sent (if required)	
Trending Search:		Trigger	
Trending Strategy		Trigger Reached	
Pre-Triage Recommendation	Trending & Surveillance by [redacted] on 28/10/2021		
Pre-Triage Comments		Change Recommendation why:	
Triage Decision	Trending & Surveillance by [redacted] on 28/10/2021		
Triage Comments			

Safety Publications

Safety Warning Decision Record

FSN / SWDR 1

SWDR 1 : Problem Definition

SWDR 1 : Details of Mfrs corrective actions

SWDR 1 : MHRA Action

SWDR 1 : Unit Sign Off

SWDR 1 : TMG Reviews

SWDR 1 : Change Request

FSN / SWDR 2

SWDR 2: Problem Definition

SWDR 2: Details of Mfrs corrective actions

SWDR 2: MHRA Action

SWDR 2: Unit Sign Off

SWDR 2: TMG Reviews

SWDR 2: Change Request

FSN / SWDR 3

SWDR 3 : Problem Definition

SWDR 3 : Details of Mfrs corrective actions

SWDR 3 : MHRA Action

SWDR 3 : Unit Sign Off

SWDR 3 : TMG Reviews

SWDR 3 : Change Request

Correspondence

Default Adress for Letters	Manufacturer

Workflow:		Acknowledgement sent:		Conclusion Letters sent :		Trending & Surveillance letter sent :	
Data Input Complete	28/10/2021	Reporter		Reporter		Reporter	
Pre-Triage Complete	28/10/2021	Manufacturer		Manufacturer		Manufacturer	28/10/2021
Triage Complete	28/10/2021	Supplier		Supplier		Supplier	
Received in AIC from Unit		Authorised Rep		Authorised Rep		Authorised Rep	
				No Letter Required			
				By:			
				On:			

Manufacturer's Interim Response:		Manufacturer's Final Response:		Reminders:		Referred Out:	
Received		Received	03/03/2022	Is a reminder required?	Yes	Agreed to Refer Out	
Passed to Unit Admin for scanning		Rationale for Not Reporting Received		Earliest date for next reminder		Letter Sent on	
Attached to AITS Record		Attached to AITS Record					
Passed to RO		Passed to RO	03/03/2022				
Received by RO		Received by RO	03/03/2022				
		Returned with closure decision					
Alternative Initial Letter			MTS Letter				

Initial:		First Reminder:		Second Reminder:		Third Reminder:	
Date Sent		Date Sent		Date Sent		Date Sent	
Reply Due		Reply Due		Reply Due		Reply Due	
Reply Received		Reply Received		Reply Received		Reply Received	

Conclusion

(Click here for IMDRF Help)

Failure Cause

Failure Effect

Conclusion

Conclude as no confirmed device problem

Concluded Responsibility *

Cause Investigation

Type of Investigation 1 *	B22 - Insufficient Information Available	Type of Investigation 2 *	
Type of Investigation 3 *		Type of Investigation 4 *	
Type of Investigation 5 *		Type of Investigation 6 *	
Type of Investigation 7 *		Type of Investigation 8 *	

Investigation Findings 1 (Level 1) *	C20 - No Findings Available	Investigation Findings 1 (Level 2) *	-	Investigation Findings 1 (Level 3) *	-	Concluded MHRA specific	
Investigation Findings 2 (Level 1) *		Investigation Findings 2 (Level 2) *		Investigation Findings 2 (Level 3) *			
Investigation Findings 3 (Level 1) *		Investigation Findings 3 (Level 2) *		Investigation Findings 3 (Level 3) *			
Investigation Findings 4 (Level 1) *		Investigation Findings 4 (Level 2) *		Investigation Findings 4 (Level 3) *			
Investigation Findings 5 (Level 1) *		Investigation Findings 5 (Level 2) *		Investigation Findings 5 (Level 3) *			
Investigation Findings 6 (Level 1) *		Investigation Findings 6 (Level 2) *		Investigation Findings 6(Level 3) *			
Investigation Conclusion 1 (Level 1) *	D15 - Cause Not Established	Investigation Conclusion 1 (Level 2) *	-				
Investigation Conclusion 2 (Level 1) *		Investigation Conclusion 2 (Level 2) *					
Investigation Conclusion 3 (Level 1) *		Investigation Conclusion 3 (Level 2) *					
Investigation Conclusion 4 (Level 1) *		Investigation Conclusion 4 (Level 2) *					
Investigation Conclusion 5 (Level 1) *		Investigation Conclusion 5(Level 2) *					

Investigation Conclusion 6 (Level 1) *

Investigation Conclusion 6 (Level 2) *

If you think the incident is unique and a suitable IMDRF term is missing, briefly explain

Concluded Clinical Risk *

Concluded as vigilance? *

Outcome *

Manufacturers Preliminary Analysis:

At this time, we have only received that there are three additional cases with product Histoacryl (reference [redacted] . We have requested additional information such as description of the event, type of surgery, when it occurred, batch number involved,... The results will be provided in the Final Report.

Initial Corrective Action:

No corrective/preventive actions are implemented at this moment.

Manufacturers Device Analysis Results:

Remedial Action/Corrective Action/Preventive Action:

Final (Non-reportable incident)

==========

No remedial/corrective/preventive and Field Safety Corrective Actions are applicable at this time.

Manufacturers Final Comments:

Final (Non-reportable incident)

==========

Without samples or more information a suitable analysis cannot be performed. Nevertheless, we take note of this incidence and if any sample or more information is received in the future, we will re-open the case and analyse it.

For Final (Non-reportable Incidents) fill out rationale for why this is considered not reportable

We have only received that there are three additional cases with product Histoacryl (reference [redacted] but no further data has been provided regarding these cases.

The involved batch number or possible batches have not been received. As no batch number is available, the batch manufacturing record cannot be reviewed.

On the other hand, without samples or more information, we are not in position of studying if the involved product does not fulfil the specifications. In consequence, a proper analysis cannot be done and the case is not confirmed due to lack of evidence. Nevertheless, we take note of this incidence and if any sample or more information is received in the future, we will re-open the case and analyse it.

Is root cause confirmed? No

Has the risk assessment been reviewed? Yes

If 'No' rationale for no review required

If the risk assessment has been reviewed, is it still adequate? Yes

Risk Assessment result

The residual risk of Histoacryl not being functional is accepted for all approved indications.

Manufacturers Time Schedule for the implementation of identified actions

Long Term

Corrective Action Agreed

Clinical Follow-up Required

Further Investigations Planned

In waiting to receive additional information of the cases.

Conclusion Description: *

NoNoNo No

Select MTS Letter

RO agrees complete and ready to move to surveillance

[redacted]

Date Investigation Completed *

Date File Closed & moved to Surveillance 28/10/2021

No MHRA (Devices) investigation required. Incident referred out to:

Adverse Event Type Codes

Adverse Event Cause Codes

FDA Adverse Event Term

Distribution of Incident report/FSCA:

EEA & Switzerland GB

Candidate Countries

Outside EEA, Switzerland & Candidate Countries

Similar Incidents

SIMILAR INCIDENTS(FOR FINAL(REPORTABLE INCIDENTS))				
Use of IMDRF Terms and Codes for identifying similar Incidents				
Identification of similar Incidents using IMDRF Adverse Event Reporting terms and Codes				
IMDRF Code relating to most relevant 'Medical device Problem'				
IMDRF Code relating to most relevant 'Investigation finding'				
if other, - Enter the description of what similar Incidents are based on and rationale why the above IMDRF codes were not used				
Use of in-house terms/codes for identifying similar Incidents				
If similar incidents were not identified by IMDRF codes but by in-house code,please provide the codes and terms below:				
Code/Term for most relevant medical device problem				
Code				
Term				
Code/Term for most relevant root cause evaluation				
Code				

Term				
If other- enter description of what similiar incidents are based on and the rationale why the above codes were not used				
Number of Similar Incidents and devices on Market				
Indicate on which basis similar incidents are identified regarding the device or device variant				
Details of the above selected				
Indicate to what criteria the number of devices on the market (also known as denominator data) is based on:				
If other please describe				
Enter the number of similar incidents and devices on market for the indicated time periods unless: A. different period has been specified by European Vigilance Working Groups B. the device has not been on the European Market for more than three years TIMEPERIOD N Year to date = incident year (e.g. 2012-10-23)				
Start Date	01 /01 /2022			
End Date				
	No of Similar Incients	No of Devices on Market		
Country of incident				
EEA + CH + TR				
World				
TIMEPERIOD N-1 calendar year one year before incident (e.g. 2012-10-23)				
Start Date	01 /01 /2021			
End Date				
	No of Similar Incients	No of Devices on Market		
Country of incident				
EEA + CH + TR				
World				

TIMEPERIOD N-2 calendar year two years before incident (e.g. 2012-10-23)				
Start Date	01 /01 /2020			
End Date				
	No of Similar Incients	No of Devices on Market		
Country of incident				
EEA + CH + TR				
World				
TIMEPERIOD N-3 calendar year three years before incident (e.g. 2012-10-23)				
Start Date	01 /01 /2019			
End Date				
	No of Similar Incients	No of Devices on Market		
Country of incident				
EEA + CH + TR				
World				
Comments on how similar incidents and associated number of devices on market were determined				