EUROPEAN
COMMISSION

Brussels, 16.1.2023
SWD(2023) 19 final

COMMISSION STAFF WORKING DOCUMENT

Annual overview of devices subject to the clinical evaluation consultation procedure pursuant to Article 54(4) of Regulation (EU) 2017/745 on medical devices (April 2021-June 2022)

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1. Introduction

Regulation (EU) 2017/745 on medical devices[1] (MDR) entered into force in May 2017 with effect from 26 May 2021.

According to Article 54 of the MDR, a notified body (NB) shall follow a clinical evaluation consultation procedure (CECP) when performing a conformity assessment of certain high-risk devices, namely class III implantable devices and class IIb active devices intended to administer and/or remove a medicinal product (ARMP devices). The purpose of the Clinical Evaluation Consultation Procedure (CECP) is the provision of independent scientific opinions by expert panels designated pursuant to Commission Implementing Decision (EU) 2019/1396[2] on the NB's clinical evaluation assessment report (CEAR) based on the manufacturer's clinical evidence.

Article 54(2) of the MDR outlines three exemptions from the obligation for the notified bodies to follow a CECP. According to Article 54(3) of the MDR, for each device falling within the scope of the CECP, the notified body should send a notification accompanied by the clinical evaluation assessment report to the competent authorities, the authority responsible for notified bodies and the Commission with a justification whether or not the CECP applies to the respective device.

Files containing relevant documents pertaining to devices not exempted from the CECP are transmitted to the expert panels but, depending on the screening panel's decision, not all CECP applications will necessarily result in a scientific opinion. Panel Experts decide on the basis of three criteria outlined in Annex IX Section 5.1 point (c) MDR whether or not to provide an opinion in response to a consultation. A NB receiving an opinion from the expert panels is required to duly consider the advice and where necessary take appropriate actions (MDR Annex IX Section 5(1)). In case the NB does not follow the advice of the panel, it needs to provide a full justification in its conformity assessment report, justification which the Commission shall make publicly available via Eudamed alongside the panel's opinion.

According to Article 54(4) of the MDR, the Commission will draw up an annual overview of devices which have been subject to the CECP, including:

- for all devices in scope of the CECP, a listing of notifications by NBs on whether or not the CECP applies;
- for all devices not exempted from the CECP, a listing of those for which the expert panels decided to provide an opinion;
- for all devices subject to an opinion from the expert panels, a listing of the cases where the NB did not follow the advice from the expert panel.

The first annual overview covers the relevant activities of the expert panels from their start date[3] until 30 June 2022.

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745
[2] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019D1396&from=EN
[3] The expert panels have been accepting CECP submissions from notified bodies since April 2021

2. Notifications by notified bodies on whether or not the CECP applies

For each device falling under the scope of Article 54(1) of the MDR, the NB should send a notification to the competent authorities, the authority responsible for notified bodies and the Commission through Eudamed[4] whether or not the CECP applies to a specific device pursuant to the requirement set in (Article 54(3) of the MDR). If the CECP does not apply because the derogation criteria are met, the NB is asked to indicate the reason (a, b or c) corresponding to the respective exemption listed under paragraph (2) of the same Article, namely:

a) this is a renewal of a certificate issued under the MDR without modification of the device;

b) the device has been designed by modifying a device already marketed by the same manufacturer for the same intended purpose and the modifications do not adversely affect the benefit-risk ratio of the device[5];

c) the principles of the clinical evaluation of the device type or category have been addressed in a Common Specification (CS) referred to in Article 9 of the MDR and the clinical evaluation of the manufacturer for this device is in compliance with the relevant CS for clinical evaluation of that kind of device.

Until 30 June 2022, 215 notifications under Article 54(3) of the MDR were sent by 8 NBs. Listings of these notifications are reported in Annex 1 (devices for which CECP applies) and Annex 2 (devices exempted from the CECP).

2.1. Devices for which the CECP was applied

NBs declared that the CECP was applied to 24 out of the 215 notified devices, i.e. 11% of all devices falling within the CECP scope according to Article 54(1). Twenty-one of these 24 devices (87,5%) were Class III implantable devices and 3 of them (12,5%) were Class IIb ARMP devices. A description of these devices according to EMDN type is provided in Table 1. The majority (58,4%) fell within 3 main categories:

- implantable cardiac devices such as pacemakers, defibrillators and insertable cardiac monitors (25,0%);
- vascular and cardiac prostheses (16,7%);
- orthopaedic prostheses (16,7%).

Table 1. Description of devices to which the CECP was applied (n=24)

Class III implantable devices	**21**	**87,5%**
C: Cardiocirculatory system devices	**2**	**8,4%**
C01: Arterio-venous system devices	1	4,2%

[4] Until Eudamed is fully functional, the secure CIRCABC notifications replace those foreseen in the MDR to be managed via EUDAMED (see Commission Guidance at: https://ec.europa.eu/health/system/files/2021-05/2021-1_guidance-administrative-practices_en_0.pdf).

[5] See for clarifications the latest revision of the MDCG document 2019-3 on Article 54(2)b at: https://ec.europa.eu/health/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en

C90: Cardiocirculatory devices - various	1	4,2%
J: Active-implantable devices	**8**	**33,3%**
J01: Cardiac functionality implantable devices	6	25,0%
J02: Implantable neurostimulators	1	4,2%
J06: Active implantable glucose monitoring systems	1	4,2%
P: Implantable prosthetic and osteosynthesis devices	**11**	**45,8%**
P06: Breast implants	1	4,2%
P07: Vascular and cardiac prostheses	4	16,7%
P09: Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	4	16,7%
P90: Implantable prosthetic and osteosynthesis devices - various	2	8,3%
Class IIb ARMP devices	**3**	**12,5%**
Z: Medical equipment and related accessories, software and consumables	**3**	**12,5%**
Z12: Instruments for functional explorations and therapeutic interventions	3	12,5%

2.2. Devices that were exempted from the CECP

According to NBs' notifications, 191 out of the 215 devices falling within the scope of CECP requirement as set in Article 54 of MDR (88,9%) were actually exempted from the CECP. Among these 191 devices, 170 (89,0%) were class III implantable devices and 21 (11,0%) class IIb ARMP devices. A description of these devices according to EMDN type is provided in Table 2. The majority of CECP exempted devices (56,0%) fell within 3 main categories:

- orthopaedic implants (23,0%);
- surgical meshes, structures filling and tissue patches (17,8%);
- vascular and cardiac prostheses (15,2%).

The reason for exemption was in all cases modifications of a device already marketed by the same manufacturer for the same intended purpose with modifications that do not adversely affect the benefit-risk ratio (Article 54(2)b).

Table 2. Description of medical devices exempted from the CECP (n=191)

Class III implantable devices	**170**	**89,0%**
C: Cardiocirculatory system devices	**8**	**4,2%**
C01: Arterio-venous system devices	8	4,2%
F: Dialysis devices	**2**	**1,0%**
F90: Dialysis devices - various	2	1,0%
H: Suture devices	**17**	**8,9%**
H01: Surgical sutures	12	6,3%
H02: Mechanical surgical staplers	2	1,0%
H03: Haemostasis clips	1	0,5%
H90: Suture devices - various	2	1,0%
J: Active-implantable devices	**19**	**9,9%**
J01: Cardiac functionality implantable devices	10	5,2%
J02: Implantable neurostimulators	3	1,6%
J03: Auditory active-implantable devices	6	3,1%
M: Devices for general and specialist dressings	**6**	**3,1%**
M04: Special dressings	6	3,1%
P: Implantable prosthetic and osteosynthesis devices	**112**	**58,6%**
P02: Ent prostheses	2	1,0%
P03: Ocular prostheses	1	0,5%
P06: Breast implants	2	1,0%
P07: Vascular and cardiac prostheses	29	15,2%
P09: Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	44	23,0%
P90: Implantable prosthetic and osteosynthesis devices - various	34	17,8%
Q: Dental, ophthalmologic and ent devices	**2**	**1,0%**
Q01: Dental devices	1	0,5%
Q03: Ent devices	1	0,5%

Z: Medical equipment and related accessories, software and consumables	**4**	**2,1%**
Z12: Instruments for functional explorations and therapeutic interventions	4	2,1%
Class IIb ARMP devices	**21**	**11,0%**
A: Devices for administration, withdrawal and collection	**4**	**2,1%**
A02: Syringes	1	0,5%
A03: Tubular devices	2	1,0%
A07: Adapters, connectors, ramps, stopcocks, caps	1	0,5%
F: Dialysis devices	**1**	**0,5%**
F04: Dialysis concentrates	1	0,5%
Z: Medical equipment and related accessories, software and consumables	**16**	**8,4%**
Z11: Bioimaging and radiotherapy instruments	2	1,0%
Z12: Instruments for functional explorations and therapeutic interventions	14	7,3%

3. CECP applications leading to an opinion by the expert panels

Until 30 June 2022, 24 CECP applications were submitted to the Secretariat of the expert panels[6]. Experts took the decision to provide an opinion for 6 of them (25,0%). On 30 June 2022, 5 opinions were delivered by the expert panels and one opinion was still under development.

Opinions are available on the Commission's website:

https://health.ec.europa.eu/medical-devices-expert-panels/experts/list-opinions-provided-under-cecp_en

Details of the files for which experts decided to provide an opinion are reported in Table 3.

[6] The Secretariat of the expert panels was transferred from the Joint Research Center of the Commission to the European Medicines Agency on 01 March 2022 in application of Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L:2022:020:FULL&from=EN

Table 3. Listing of CECP applications where an opinion by the expert panels was delivered

NB number	NB name	EMDN device type	Risk class / type	Reason for submission	Main reason supporting the decision
0483	MDC	P9004: Structures filling, replacement and reconstruction devices	class III implantable	new MDR device	criterion 1: novelty and clinical/health impact
0344	DEKRA (NL)	P0703: Cardiac valves	class III implantable	new MDR device	criterion 1: novelty and clinical/health impact
0344	DEKRA (NL)	P0703: Cardiac valves	class III implantable	new intended purpose	criterion 1: novelty and clinical/health impact
0344	DEKRA (NL)	P0703: Cardiac valves	class III implantable	new MDR device	criterion 1: novelty and clinical/health impact
0344	DEKRA (NL)	J0201: Cerebral implantable neurostimulators	class III implantable	new MDR device	criterion 1: novelty and clinical/health impact
2797	BSI	P0908: Hip prostheses	class III implantable	modified device	criterion 1: novelty and clinical/health impact

4. Cases where notified bodies did not follow the advice from the expert panels

Until 30 June 2022, the expert panels delivered 5 opinions. The Secretariat of the expert panels did not receive any justification from NBs in case of a decision not to follow the scientific advice provided by the expert panels while conducting the completion of the certification process. This implies that for the finalised certifications the notified bodies followed the advice of the expert panels.

5. Summary

In summary, since the start of the expert panels' activities in April 2021 until 30 June 2022, 215 notifications under Article 54(3) were sent by NBs. The CECP was applied to 24 of these devices (11,2%). All other devices (191/215, 88,9%) were exempted from the CECP according to Article 54(2)b.

The experts screened 24 CECP applications and decided to provide an opinion for 6 out of the 24 CECP applications received (25,0%). On 30 June 2022, 5 opinions were delivered by the

expert panels and one opinion was still under development. The secretariat did not receive any justification from NBs not following the advice provided by the expert panel.

Annex 1: Listing of notifications under Article 54(3) of the MDR – medical devices for which the CECP was applied

NB number	NB name	EMDN type - level 3	Risk class / type
0123	TUV-SUD	J0101: Implantable pacemakers	Class III implantable
0123	TUV-SUD	J0105: Implantable defibrillators	Class III implantable
0123	TUV-SUD	J0190: Implantable cardiac devices – various	Class III implantable
0123	TUV-SUD	J0190: Implantable cardiac devices – various	Class III implantable
0123	TUV-SUD	J0190: Implantable cardiac devices – various	Class III implantable
0123	TUV-SUD	P9004: Structures filling, replacement and reconstruction devices	Class III implantable
0123	TUV-SUD	Z1203: Instruments to support and monitor vital signs	Class IIb ARMP
0123	TUV-SUD	Z1203: Instruments to support and monitor vital signs	Class IIb ARMP
0123	TUV-SUD	Z1209: Nephrology and haemodialysis instruments	Class IIb ARMP
0344	DEKRA (NL)	J0201: Cerebral implantable neurostimulators	Class III implantable
0344	DEKRA (NL)	P0703: Cardiac valve	Class III implantable
0344	DEKRA (NL)	P0703: Cardiac valve	Class III implantable
0344	DEKRA (NL)	P0703: Cardiac valve	Class III implantable
0459	GMED	P0704: Vascular and cardiac endoprostheses	Class III implantable
0483	MDC	P9004: Structures Filling, Replacement	Class III

		and Reconstruction Devices	implantable
2797	BSI	C0104: Angiography and haemodynamic devices	Class III implantable
2797	BSI	C9001: Haemostasis valves and systems	Class III implantable
2797	BSI	J0102: Implantable cardiac diagnostic devices	Class III implantable
2797	BSI	J0601: Implantable glucose monitoring sensors	Class III implantable
2797	BSI	P0601: Permanent non-expandable breast implants	Class III implantable
2797	BSI	P0901: Shoulder prostheses	Class III implantable
2797	BSI	P0908: Hip prostheses	Class III implantable
2797	BSI	P0908: Hip prostheses	Class III implantable
2797	BSI	P0912: Osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable

Annex 2: Listing of notifications under Article 54(3) of the MDR – medical devices exempted from the CECP

Medical Devices exempted from the CECP requirement are medical devices for which CECP requirement should apply according to Art. 54(1) but for which the CECP was not applied by notified bodies, due to one or more of the exemption criteria set out in Art. 54(2).

NB number	NB name	EMDN type - level 3	Risk class / type	Reason for CECP exemption
0123	TUV-SUD	A0202: Reusable syringes	Class IIb ARMP	MDR Art 54(2)b
0123	TUV-SUD	F0402: Dialysis concentrates, basic solutions	Class IIb ARMP	MDR Art 54(2)b
0123	TUV-SUD	F9002: Vascular access devices (only for haemodialysis)	Class III implantable	MDR Art 54(2)b
0123	TUV-SUD	H0101: Absorbable sutures	Class III implantable	MDR Art 54(2)b
0123	TUV-SUD	J0101: Implantable pacemakers	Class III implantable	MDR Art 54(2)b
0123	TUV-SUD	J0102: Implantable cardiac diagnostic devices	Class III implantable	MDR Art 54(2)b
0123	TUV-SUD	J0105: Implantable defibrillators	Class III implantable	MDR Art 54(2)b
0123	TUV-SUD	J0190: Implantable cardiac devices - various	Class III implantable	MDR Art 54(2)b
0123	TUV-SUD	J0202: Spinal implantable neurostimulators	Class III implantable	MDR Art 54(2)b
0123	TUV-SUD	J0299: Implantable neurostiimulators - other	Class III implantable	MDR Art 54(2)b
0123	TUV-SUD	J0301: Cochlear implantable devices	Class III implantable	MDR Art 54(2)b
0123	TUV-SUD	J0301: Cochlear implantable devices	Class III implantable	MDR Art 54(2)b
0123	TUV-SUD	J0301: Cochlear implantable devices	Class III	MDR Art

			implantable	54(2)b
0123	TUV-SUD	J0301: Cochlear implantable devices	Class III implantable	MDR Art 54(2)b
0123	TUV-SUD	J0380: AUDITORY ACTIVE-IMPLANTABLE DEVICES - ACCESSORIES	Class III implantable	MDR Art 54(2)b
0123	TUV-SUD	J0399: AUDITORY ACTIVE-IMPLANTABLE DEVICES - OTHER	Class III implantable	MDR Art 54(2)b
0123	TUV-SUD	P0909: Knee prostheses	Class III implantable	MDR Art 54(2)b
0123	TUV-SUD	P9004: Structures filling, replacement and reconstruction devices	Class III implantable	MDR Art 54(2)b
0123	TUV-SUD	P9004: Structures filling, replacement and reconstruction devices	Class III implantable	MDR Art 54(2)b
0123	TUV-SUD	P9004: Structures filling, replacement and reconstruction devices	Class III implantable	MDR Art 54(2)b
0123	TUV-SUD	Q0103: Surgical dental devices	Class III implantable	MDR Art 54(2)b
0123	TUV-SUD	Z1203: Instruments to support and monitor vital signs	Class IIb ARMP	MDR Art 54(2)b
0123	TUV-SUD	Z1203: Instruments to support and monitor vital signs	Class IIb ARMP	MDR Art 54(2)b
0123	TUV-SUD	Z1203: Instruments to support and monitor vital signs	Class IIb ARMP	MDR Art 54(2)b
0123	TUV-SUD	Z1203: Instruments to support and monitor vital signs	Class IIb ARMP	MDR Art 54(2)b
0123	TUV-SUD	Z1203: Instruments to support and monitor vital signs	Class IIb ARMP	MDR Art 54(2)b
0123	TUV-SUD	Z1203: Instruments to support and monitor vital signs	Class IIb ARMP	MDR Art 54(2)b
0123	TUV-SUD	Z1204: General medicine instruments	Class IIb ARMP	MDR Art 54(2)b
0123	TUV-SUD	Z1205: Cardiology and cardiosurgery instruments	Class IIb ARMP	MDR Art 54(2)b

0123	TUV-SUD	Z1209: Nephrology and haemodialysis instruments	Class IIb ARMP	MDR Art 54(2)b
0123	TUV-SUD	Z1209: Nephrology and haemodialysis instruments	Class IIb ARMP	MDR Art 54(2)
0124	DEKRA (DE)	P9002: Surgical meshes	Class III implantable	MDR Art 54(2)b
0197	TÜV Rheinland	P0912: Osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art 54(2)b
0197	TÜV Rheinland	P0912: Osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art 54(2)b
0197	TÜV Rheinland	P9004: Structures filling, replacement and reconstruction devices	Class III implantable	MDR Art 54(2)b
0297	DQS Medizinprodukte	C0104: Angiography and haemodynamic devices	Class III implantable	MDR Art 54(2)b
0297	DQS Medizinprodukte	C0104: Angiography and haemodynamic devices	Class III implantable	MDR Art 54(2)b
0297	DQS Medizinprodukte	P0301: Intraocular lenses (iol)	Class III implantable	MDR Art 54(2)b
0297	DQS Medizinprodukte	P0704: Vascular and cardiac endoprostheses	Class III implantable	MDR Art 54(2)b
0297	DQS Medizinprodukte	Z1203: Instruments to support and monitor vital signs	Class III implantable	MDR Art 54(2)b
0297	DQS Medizinprodukte	Z1210: Neurology and neurosurgery instruments	Class III implantable	MDR Art 54(2)b
0297	DQS Medizinprodukte	Z1210: Neurology and neurosurgery instruments	Class III implantable	MDR Art 54(2)b
0344	DEKRA (NL)	P0703: Cardiac valves	Class III implantable	MDR Art. 54(2)b
0344	DEKRA (NL)	P070301030101, Stented biological aortic valves for percutaneous implant - valve tissue of animal origin use	Class III implantable	MDR Art. 54(2)b
0344	DEKRA (NL)	Q0301: Nasopharyngeal devices	Class III implantable	MDR Art. 54(2)b

0459	GMED	P0704: Vascular and cardiac endoprostheses	Class III implantable	MDR Art 54(2)b
0459	GMED	P0907: Spine stabilisation prostheses and systems	Class III implantable	MDR Art 54(2)b
0459	GMED	P0907: Spine stabilisation prostheses and systems	Class III implantable	MDR Art 54(2)b
0459	GMED	P0908: Hip prostheses	Class III implantable	MDR Art 54(2)b
0459	GMED	P0908: Hip prostheses	Class III implantable	MDR Art 54(2)b
0459	GMED	P0908: Hip prostheses	Class III implantable	MDR Art 54(2)b
0459	GMED	P0908: Hip prostheses	Class III implantable	MDR Art 54(2)b
0459	GMED	P0908: Hip prostheses	Class III implantable	MDR Art 54(2)b
0459	GMED	P0908: Hip prostheses	Class III implantable	MDR Art 54(2)b
0459	GMED	P9004: Structures filling, replacement and reconstruction devices	Class III implantable	MDR Art 54(2)b
0483	MDC	H0101: Absorbable Sutures	Class III implantable	MDR Art 54(2)b
0483	MDC	H0101: Absorbable Sutures	Class III implantable	MDR Art 54(2)b
0483	MDC	H0101: Absorbable Sutures	Class III implantable	MDR Art 54(2)b
0483	MDC	P0907: Spine Stabilisation Prostheses and Systems	Class III implantable	MDR Art 54(2)b
0483	MDC	P0909: Knee Prostheses	Class III implantable	MDR Art 54(2)b
0483	MDC	P9004: Structures Filling, Replacement and Reconstruction Devices	Class III implantable	MDR Art 54(2)b
2797	BSI	A0303: Rapid infusion systems (high flow)	Class IIb ARMP	MDR Art

				54(2)b
2797	BSI	A0304: Administration kits	Class IIb ARMP	MDR Art 54(2)b
2797	BSI	A0704: Systems for reconstitution and administration of pharmaceuticals	Class IIb ARMP	MDR Art 54(2)b
2797	BSI	C0102: Central i.v. catheters	Class III implantable	MDR Art 54(2)b
2797	BSI	C0102: Central i.v. catheters	Class III implantable	MDR Art 54(2)b
2797	BSI	C0104: Angiography and haemodynamic devices	Class III implantable	MDR Art 54(2)b
2797	BSI	C0104: Angiography and haemodynamic devices	Class III implantable	MDR Art 54(2)b
2797	BSI	C0104: Angiography and haemodynamic devices	Class III implantable	MDR Art 54(2)b
2797	BSI	C0105: Intravascular protection devices	Class III implantable	MDR Art 54(2)b
2797	BSI	F9002: Vascular access devices (only for haemodialysis)	Class III implantable	MDR Art 54(2)b
2797	BSI	H0101: Absorbable sutures	Class III implantable	MDR Art 54(2)b
2797	BSI	H0101: Absorbable sutures	Class III implantable	MDR Art 54(2)b
2797	BSI	H0101: Absorbable sutures	Class III implantable	MDR Art 54(2)b
2797	BSI	H0101: Absorbable sutures	Class III implantable	MDR Art 54(2)b
2797	BSI	H0102: Non-absorbable sutures	Class III implantable	MDR Art 54(2)b
2797	BSI	H0102: Non-absorbable sutures	Class III implantable	MDR Art 54(2)b
2797	BSI	H0102: Non-absorbable sutures	Class III implantable	MDR Art 54(2)b

2797	BSI	H0102: Non-absorbable sutures	Class III implantable	MDR Art 54(2)b
2797	BSI	H0203: Staplers for videosurgery; H0202: Staplers, open surgery	Class III implantable	MDR Art 54(2)b
2797	BSI	H0299: Mechanical surgical staplers - other	Class III implantable	MDR Art 54(2)b
2797	BSI	H0301: Haemostasis clips for open surgery	Class III implantable	MDR Art 54(2)b
2797	BSI	H9003: Suture reinforcement or support devices	Class III implantable	MDR Art 54(2)b
2797	BSI	H9080: Suture accessories	Class III implantable	MDR Art 54(2)b
2797	BSI	J0105: Implantable defibrillators	Class III implantable	MDR Art 54(2)b
2797	BSI	J0105: Implantable defibrillators	Class III implantable	MDR Art 54(2)b
2797	BSI	J0105: Implantable defibrillators	Class III implantable	MDR Art 54(2)b
2797	BSI	J0105: Implantable defibrillators	Class III implantable	MDR Art 54(2)b
2797	BSI	J0105: Implantable defibrillators	Class III implantable	MDR Art 54(2)b
2797	BSI	J0190: Implantable cardiac devices - various	Class III implantable	MDR Art 54(2)b
2797	BSI	J0202: Spinal implantable neurostimulators	Class III implantable	MDR Art 54(2)b
2797	BSI	M0405: Haemostatic dressings	Class III implantable	MDR Art 54(2)b
2797	BSI	M0405: Haemostatic dressings	Class III implantable	MDR Art 54(2)b
2797	BSI	M0405: Haemostatic dressings	Class III implantable	MDR Art 54(2)b
2797	BSI	M0405: Haemostatic dressings	Class III	MDR Art

			implantable	54(2)b
2797	BSI	M0405: Haemostatic dressings	Class III implantable	MDR Art 54(2)b
2797	BSI	M0406: Dressings for the prevention of post-operative adhesions	Class III implantable	MDR Art 54(2)b
2797	BSI	P0202: Rhinology prostheses	Class III implantable	MDR Art 54(2)b
2797	BSI	P0202: Rhinology prostheses	Class III implantable	MDR Art 54(2)b
2797	BSI	P0601: Permanent, non-expandable breast implants	Class III implantable	MDR Art 54(2)b
2797	BSI	P0601: Permanent, non-expandable breast implants	Class III implantable	MDR Art 54(2)b
2797	BSI	P0701: Vascular prostheses	Class III implantable	MDR Art 54(2)b
2797	BSI	P0701: Vascular prostheses	Class III implantable	MDR Art 54(2)b
2797	BSI	P0701: Vascular prostheses	Class III implantable	MDR Art 54(2)b
2797	BSI	P0702: Vascular patches	Class III implantable	MDR Art 54(2)b
2797	BSI	P0704: Vascular and cardiac endoprostheses	Class III implantable	MDR Art 54(2)b
2797	BSI	P0704: Vascular and cardiac endoprostheses	Class III implantable	MDR Art 54(2)b
2797	BSI	P0704: Vascular and cardiac endoprostheses	Class III implantable	MDR Art 54(2)b
2797	BSI	P0704: Vascular and cardiac endoprostheses	Class III implantable	MDR Art 54(2)b
2797	BSI	P0704: Vascular and cardiac endoprostheses	Class III implantable	MDR Art 54(2)b
2797	BSI	P0704: Vascular and cardiac endoprostheses	Class III implantable	MDR Art 54(2)b

2797	BSI	P0704: Vascular and cardiac endoprostheses	Class III implantable	MDR Art 54(2)b
2797	BSI	P0704: Vascular and cardiac endoprostheses	Class III implantable	MDR Art 54(2)b
2797	BSI	P0704: Vascular and cardiac endoprostheses	Class III implantable	MDR Art 54(2)b
2797	BSI	P0704: Vascular and cardiac endoprostheses	Class III implantable	MDR Art 54(2)b
2797	BSI	P0704: Vascular and cardiac endoprostheses	Class III implantable	MDR Art 54(2)b
2797	BSI	P0704: Vascular and cardiac endoprostheses	Class III implantable	MDR Art 54(2)b
2797	BSI	P0704: Vascular and cardiac endoprostheses	Class III implantable	MDR Art 54(2)b
2797	BSI	P0704: Vascular and cardiac endoprostheses	Class III implantable	MDR Art 54(2)b
2797	BSI	P0704: Vascular and cardiac endoprostheses	Class III implantable	MDR Art 54(2)b
2797	BSI	P0704: Vascular and cardiac endoprostheses	Class III implantable	MDR Art 54(2)b
2797	BSI	P0704: Vascular and cardiac endoprostheses	Class III implantable	MDR Art 54(2)b
2797	BSI	P0704: Vascular and cardiac endoprostheses	Class III implantable	MDR Art 54(2)b
2797	BSI	P0704: Vascular and cardiac endoprostheses	Class III implantable	MDR Art 54(2)b
2797	BSI	P0704: Vascular and cardiac endoprostheses	Class III implantable	MDR Art 54(2)b
2797	BSI	P0704: Vascular and cardiac endoprostheses	Class III implantable	MDR Art 54(2)b
2797	BSI	P0901: Shoulder prostheses	Class III implantable	MDR Art 54(2)b
2797	BSI	P0901: Shoulder prostheses	Class III	MDR Art

			implantable	54(2)b
2797	BSI	P0908: Hip prostheses	Class III implantable	MDR Art 54(2)b
2797	BSI	P0908: Hip prostheses	Class III implantable	MDR Art 54(2)b
2797	BSI	P0908: Hip prostheses	Class III implantable	MDR Art 54(2)b
2797	BSI	P0908: Hip prostheses	Class III implantable	MDR Art 54(2)b
2797	BSI	P0908: Hip prostheses	Class III implantable	MDR Art 54(2)b
2797	BSI	P0908: Hip prostheses	Class III implantable	MDR Art 54(2)b
2797	BSI	P0908: Hip prostheses	Class III implantable	MDR Art 54(2)b
2797	BSI	P0908: Hip prostheses	Class III implantable	MDR Art 54(2)b
2797	BSI	P0908: Hip prostheses	Class III implantable	MDR Art 54(2)b
2797	BSI	P0908: Hip prostheses	Class III implantable	MDR Art 54(2)b
2797	BSI	P0908: Hip prostheses	Class III implantable	MDR Art 54(2)b
2797	BSI	P0908: Hip prostheses	Class III implantable	MDR Art 54(2)b
2797	BSI	P0908: Hip prostheses	Class III implantable	MDR Art 54(2)b
2797	BSI	P0909: Knee prostheses	Class III implantable	MDR Art 54(2)b
2797	BSI	P0909: Knee prostheses	Class III implantable	MDR Art 54(2)b
2797	BSI	P0909: Knee prostheses	Class III implantable	MDR Art 54(2)b

2797	BSI	P0909: Knee prostheses	Class III implantable	MDR Art 54(2)b
2797	BSI	P0909: Knee prostheses	Class III implantable	MDR Art 54(2)b
2797	BSI	P0909: Knee prostheses	Class III implantable	MDR Art 54(2)b
2797	BSI	P0909: Knee prostheses	Class III implantable	MDR Art 54(2)b
2797	BSI	P0909: Knee prostheses	Class III implantable	MDR Art 54(2)b
2797	BSI	P0909: Knee prostheses	Class III implantable	MDR Art 54(2)b
2797	BSI	P0909: Knee prostheses	Class III implantable	MDR Art 54(2)b
2797	BSI	P0912: Osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art 54(2)b
2797	BSI	P0912: Osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art 54(2)b
2797	BSI	P0912: Osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art 54(2)b
2797	BSI	P0990: Orthopaedic prostheses - various	Class III implantable	MDR Art 54(2)b
2797	BSI	P099001: Orthopaedic prostheses cements and accessories for mixing	Class III implantable	MDR Art 54(2)b
2797	BSI	P0999: Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis - other	Class III implantable	MDR Art 54(2)b
2797	BSI	P9002 - Surgical Mesh	Class III implantable	MDR Art 54(2)b
2797	BSI	P9002 - Surgical Mesh	Class III implantable	MDR Art 54(2)b
2797	BSI	P9002: Surgical meshes	Class III implantable	MDR Art 54(2)b

2797	BSI	P9002: Surgical meshes	Class III implantable	MDR Art 54(2)b
2797	BSI	P9002: Surgical meshes	Class III implantable	MDR Art 54(2)b
2797	BSI	P9002: Surgical meshes	Class III implantable	MDR Art 54(2)b
2797	BSI	P9002: Surgical meshes	Class III implantable	MDR Art 54(2)b
2797	BSI	P9002: Surgical meshes	Class III implantable	MDR Art 54(2)b
2797	BSI	P9002: Surgical meshes	Class III implantable	MDR Art 54(2)b
2797	BSI	P9002: Surgical meshes	Class III implantable	MDR Art 54(2)b
2797	BSI	P9002: Surgical meshes	Class III implantable	MDR Art 54(2)b
2797	BSI	P9002: Surgical meshes	Class III implantable	MDR Art 54(2)b
2797	BSI	P9002: Surgical meshes	Class III implantable	MDR Art 54(2)b
2797	BSI	P9002: Surgical meshes	Class III implantable	MDR Art 54(2)b
2797	BSI	P9002: Surgical meshes	Class III implantable	MDR Art 54(2)b
2797	BSI	P9002: Surgical meshes	Class III implantable	MDR Art 54(2)b
2797	BSI	P9002: Surgical meshes	Class III implantable	MDR Art 54(2)b
2797	BSI	P9002: Surgical meshes	Class III implantable	MDR Art 54(2)b
2797	BSI	P9002: Surgical meshes	Class III implantable	MDR Art 54(2)b
2797	BSI	P9002: Surgical meshes	Class III	MDR Art

			implantable	54(2)b
2797	BSI	P9002: Surgical meshes	Class III implantable	MDR Art 54(2)b
2797	BSI	P9003: Tissue patches	Class III implantable	MDR Art 54(2)b
2797	BSI	P9003: Tissue patches	Class III implantable	MDR Art 54(2)b
2797	BSI	P9003: Tissue patches	Class III implantable	MDR Art 54(2)b
2797	BSI	P9004: Structures filling, replacement and reconstruction devices	Class III implantable	MDR Art 54(2)b
2797	BSI	P9004: Structures filling, replacement and reconstruction devices	Class III implantable	MDR Art 54(2)b
2797	BSI	P9004: Structures filling, replacement and reconstruction devices	Class III implantable	MDR Art 54(2)b
2797	BSI	Z1103: Diagnostic and interventional radiology instruments	Class IIb ARMP	MDR Art 54(2)b
2797	BSI	Z1105: Magnetic resonance imaging (mri) instruments	Class IIb ARMP	MDR Art 54(2)b
2797	BSI	Z1203: Instruments to support and monitor vital signs	Class IIb ARMP	MDR Art 54(2)b
2797	BSI	Z1203: Instruments to support and monitor vital signs	Class IIb ARMP	MDR Art 54(2)b
2797	BSI	Z1203: Instruments to support and monitor vital signs	Class III implantable	MDR Art 54(2)b
2797	BSI	Z1203: Instruments to support and monitor vital signs	Class IIb ARMP	MDR Art 54(2)b
2797	BSI	Z1203: Instruments to support and monitor vital signs	Class IIb ARMP	MDR Art 54(2)b