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**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 (July 2022-June 2023)**

## **Contents**

List of abbreviations .....	1
1. Introduction .....	2
2. Notifications by notified bodies whether or not the CECP applies.....	3
2.1. Devices for which the CECP was applied.....	3
2.2. Devices that were exempted from the CECP .....	4
3. CECP applications leading to an opinion by the expert panels .....	7
4. Cases where notified bodies did not follow the advice from the expert panels.....	8
5. Summary .....	8
Annex 1: Listing of notifications under Article 54(3) of the MDR – devices for which the CECP was applied.....	9
Annex 2: Listing of notifications under Article 54(3) of the MDR – devices exempted from the CECP .....	12

## **List of abbreviations**

ARMP device: Active device intended to administer and/or remove medicinal product(s)

CECP: Clinical Evaluation Consultation Procedure

MDR: Medical Device Regulation

NB: Notified Body

## **1. Introduction**

Regulation (EU) 2017/745 on medical devices<sup>1</sup> (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 this consultation is the provision of independent scientific opinions by expert panels designated pursuant to Commission Implementing Decision (EU) 2019/1396<sup>2</sup> 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 is obliged to 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 second annual overview covers the activities of the expert panels from 1 July 2022 until 30 June 2023.

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<sup>1</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745>

<sup>2</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019D1396&from=EN>

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

For each device 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<sup>3</sup> 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<sup>4</sup>;
- 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.

In the reporting period, 353 notifications under Article 54(3) of the MDR were sent by 13 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 36 out of the 353 notified devices, i.e., 10,1% of all devices falling within the CECP scope according to Article 54(1). Thirty-four of these 36 devices (94,4%) were Class III implantable devices and 2 of them (5,6%) 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 4 main categories:

- cardiac functionality implantable devices (16,7%);
- orthopaedic prostheses (16,7%);
- auditory Active Implantable Devices (13,9%);
- implantable neurostimulators (11,1%).

In three cases no EMDN type was declared.

**Table 1.** Description of devices to which the CECP was applied (n=36)

Class III implantable devices	34	94,4%
C Cardiocirculatory system devices	1	2,8%
C03 Cardiac surgery and heart transplant devices	1	2,8%

<sup>3</sup> 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](https://ec.europa.eu/health/system/files/2021-05/2021-1_guidance-administrative-practices_en_0.pdf)).

<sup>4</sup> 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](https://ec.europa.eu/health/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en)

<b>H Suture Devices</b>	<b>2</b>	<b>5,6%</b>
H90 Suture devices - various	2	5,6%
<b>J Active-implantable devices</b>	<b>16</b>	<b>44,4%</b>
J01 Cardiac functionality implantable devices	6	16,7%
J02 Implantable neurostimulators	4	11,1%
J03 Auditory active-implantable devices	5	13,9%
J04 Implantable pumps	1	2,8%
<b>M Devices for general and specialist dressings</b>	<b>1</b>	<b>2,8%</b>
M04 Special dressings	1	2,8%
<b>P Implantable prosthetic and osteosynthesis devices</b>	<b>12</b>	<b>33,3%</b>
P07 Vascular and cardiac prostheses	3	8,3%
P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	6	16,7%
P90 Implantable prosthetic and osteosynthesis devices - various	3	8,3%
<b>EMDN type not reported</b>	<b>2</b>	<b>5,6%</b>
<b>Class IIb ARMP devices</b>	<b>2</b>	<b>5,6%</b>
<b>Z Medical equipment and related accessories, software and consumables</b>	<b>1</b>	<b>2,8%</b>
Z12 Instruments for functional explorations and therapeutic interventions	1	2,8%
<b>EMDN type not reported</b>	<b>1</b>	<b>2,8%</b>

## 2.2. Devices that were exempted from the CECP

According to NBs' notifications, 317 out of the 353 notified devices falling within the scope of CECP (89,8%) were exempted from the CECP. Among these 317 devices, 285 (89,9%) were Class III implantable devices and 32 (10,1%) Class IIb ARMP devices. A description of these devices according to EMDN type is provided in Table 2. The majority of CECP exempted devices (55,9%) fell within 3 main categories:

- vascular and cardiac prostheses (12,0%)
- orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis (30,0%)
- implantable prosthetic and osteosynthesis devices – various (13,9%).

In 6 cases no EMDN type was declared.

The reason for exemption was in 99,1% of the cases (314 devices) 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), in 2 cases the certificate was renewed under the MDR (0,6%) (Article 54(2)(a) and in 1 case the NB claimed that the exemption was due to common specifications being available (0,3%) (MDR Article 54(2)(c).

**Table 2.** Description of devices exempted from the CECP (n=317)

<b>Class III implantable</b>	<b>285</b>	<b>89,9%</b>
<b>A Devices for administration, withdrawal and collection</b>	<b>1</b>	<b>0,3%</b>
A01 Needles	1	0,3%
<b>C Cardiocirculatory system devices</b>	<b>18</b>	<b>5,7%</b>
C01 Arterio-venous system devices	15	4,7%
C03 Cardiac surgery and heart transplant devices	1	0,3%
C90 Cardiocirculatory devices - various	2	0,6%
<b>F Dialysis devices</b>	<b>11</b>	<b>3,5%</b>
F90 Dialysis devices - various	11	3,5%
<b>H Suture devices</b>	<b>44</b>	<b>13,9%</b>
H01 Surgical sutures	32	10,1%
H02 Mechanical surgical staplers	4	1,3%
H03 Haemostasis clips	3	0,9%
H90 Suture devices - various	5	1,6%
<b>J Active-implantable devices</b>	<b>13</b>	<b>4,1%</b>
J01 Cardiac functionality implantable devices	4	1,3%
J02 Implantable neurostimulators	6	1,9%
J04 Implantable pumps	3	0,9%
<b>M Devices for general and specialist dressings</b>	<b>2</b>	<b>0,6%</b>
M04 Special dressings	2	0,6%
<b>N Nervous and medullary systems devices</b>	<b>1</b>	<b>0,3%</b>
N01 Encephalic and peripheral nervous system devices	1	0,3%
<b>P Implantable prosthetic and osteosynthesis devices</b>	<b>181</b>	<b>57,7%</b>
P01 Facial and odontological prostheses	1	0,3%

P06 Breast implants	3	0,9%
P07 Vascular and cardiac prostheses	38	12,0%
P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	95	30,0%
P90 Implantable prosthetic and osteosynthesis devices - various	44	13,9%
<b>Q Dental, ophthalmologic and ent devices</b>	<b>7</b>	<b>2,2%</b>
Q01 Dental devices	6	1,9%
Q02 Ophthalmic devices	1	0,3%
<b>U Devices for urogenital system</b>	<b>1</b>	<b>0,3%</b>
U07 Devices for the treatment of incontinence	1	0,3%
<b>EMDN type not reported</b>	<b>6</b>	<b>1,9%</b>
<b>Class IIb ARMP devices</b>	<b>32</b>	<b>10,1%</b>
<b>A: Devices for administration, withdrawal and collection</b>	<b>2</b>	<b>0,6%</b>
A05 Mechanical infusion systems, single-use	2	0,6%
<b>R Respiratory and anaesthesia devices</b>	<b>1</b>	<b>0,3%</b>
R90 Respiratory and anaesthesia devices - various	1	0,3%
<b>Z Medical equipment and related accessories, software and consumables</b>	<b>29</b>	<b>9,1%</b>
Z11 Bioimaging and radiotherapy instruments	4	1,3%
Z12 Instruments for functional explorations and therapeutic interventions	25	7,9%

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

Between 01 July 2022 and 30 June 2023, 35 CECP applications were submitted to the Secretariat of the expert panels<sup>5</sup>. One file for which the NB assessed the CECP to be applied has not been submitted to the Secretariat yet. Experts took the decision to provide an opinion for 4 of the 35 received applications (12%). On 30 June 2023, all 4 opinions were delivered by the expert panels.

Opinions are available at the Commission's website:

[https://health.ec.europa.eu/medical-devices-expert-panels/experts/list-opinions-provided-under-cecp\\_en](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.

**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
NB 0344	DEKRA Certification B.V.	P0704: Vascular and cardiac endoprostheses	class III implantable	new MDR device	Criterion (i) Novelty and clinical/health impact
NB 2797	BSI Group The Netherlands B.V.	P9002: Surgical meshes	class III implantable	new MDR device	Criterion (ii) Scientifically valid health concerns leading to significantly adverse changes in the benefit-risk profile of a specific group / category of devices
NB 0459	GMED SAS	P0901: Shoulder prostheses	class III implantable	new intended purpose	Criterion (ii) Scientifically valid health concerns leading to significantly adverse changes in the benefit-risk profile of a specific group / category of devices
NB 0123	TÜV SÜD Product Service GmbH	J0190: Implantable cardiac devices - various	class III implantable	new MDR device	Criterion (i) Novelty and clinical/health impact

<sup>5</sup> The Secretariat of the expert panels was transferred from the Joint Research Centre 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>

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

In the reporting period, the expert panels delivered 4 opinions. The Secretariat did not receive any justification from NBs in case of a decision not to follow the scientific advice provided by the expert panels in the completion of the certification process.

#### **5. Summary**

In summary, within the reporting period from 1 July 2022 until 30 June 2023, 353 notifications under Article 54(3) were sent by NBs. The CECP was applied to 36 of these devices (10,2%). All other devices (317/353; 89,8%) were exempted from the CECP according to Article 54(2). Out of the devices exempted from the CECP, 314 (99,1%) were exempted according to Article 54(2)(b), 2 devices were exempted according to Article 54(2)(a), and a claim was made for 1 device that Article 54(2)(c) applied.

The experts screened 35 CECP applications and decided to provide an opinion for 4 out of the 35 CECP applications received (12,0%). On 30 June 2023, all 4 opinions were delivered by the expert panels. 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 – devices for which the CECP was applied**

NB number	NB	EMDN type - level 3	Risk class / type
NB 0344	DEKRA Certification B.V.	P07 Vascular and cardiac prostheses	Class III implantable
NB 0123	TÜV SÜD <sup>6</sup>	J03 Auditory active-implantable devices	Class III implantable
NB 2797	BSI <sup>7</sup>	P90 Implantable prosthetic and osteosynthesis devices - various	Class III implantable
NB 0123	TÜV SÜD	J01 Cardiac functionality implantable devices	Class III implantable
NB 2797	BSI	C03 Cardiac surgery and heart transplant devices	Class III implantable
NB 0459	GMED SAS	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable
NB 0123	TÜV SÜD	J01 Cardiac functionality implantable devices	Class III implantable
NB 0123	TÜV SÜD	J01 Cardiac functionality implantable devices	Class III implantable
NB 0123	TÜV SÜD	J02 Implantable neurostimulators	Class III implantable
NB 0123	TÜV SÜD	Non declared	Class III implantable
NB 0123	TÜV SÜD	Z12 instruments for functional explorations and therapeutic interventions	Class IIb ARMP
NB 0123	TÜV SÜD	Non declared	Class IIb ARMP
NB 0124	DEKRA Certification GmbH	H90 suture devices - various	Class III implantable
NB 0426	ITALCERT	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable
NB 0123	TÜV SÜD	P90 Implantable prosthetic and osteosynthesis devices - various	Class III implantable

<sup>6</sup> TÜV SÜD Product Service GmbH

<sup>7</sup> BSI Group The Netherlands B.V.

NB number	NB	EMDN type - level 3	Risk class / type
NB 0123	TÜV SÜD	J03 Auditory active-implantable devices	Class III implantable
NB 2797	BSI	M04 Special dressings	Class III implantable
NB 0123	TÜV SÜD	Non declared	Class III implantable
NB 0426	ITALCERT	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable
NB 0123	TÜV SÜD	J01 Cardiac functionality implantable devices	Class III implantable
NB 0123	TÜV SÜD	J01 Cardiac functionality implantable devices	Class III implantable
NB 0123	TÜV SÜD	J03 Auditory active-implantable devices	Class III implantable
NB 0344	DEKRA Certification B.V.	P07 Vascular and cardiac prostheses	Class III implantable
NB 0123	TÜV SÜD	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable
NB 0123	TÜV SÜD	J02 Implantable neurostimulators	Class III implantable
NB 0123	TÜV SÜD	P90 Implantable prosthetic and osteosynthesis devices - various	Class III implantable
NB 0123	TÜV SÜD	J04 Implantable pumps	Class III implantable
NB 0123	TÜV SÜD	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable
NB 0123	TÜV SÜD	H90 Suture devices - various	Class III implantable
NB 0123	TÜV SÜD	J03 Auditory active-implantable devices	Class III implantable
NB 0123	TÜV SÜD	J01 Cardiac functionality implantable devices	Class III implantable
NB 0123	TÜV SÜD	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable

<b>NB number</b>	<b>NB</b>	<b>EMDN type - level 3</b>	<b>Risk class / type</b>
NB 2797	BSI	P07 Vascular and cardiac prostheses	Class III implantable
NB 0123	TÜV SÜD	j02 implantable neurostimulators	Class III implantable
NB 2797	BSI	J02 Implantable neurostimulators	Class III implantable
NB 0123	TÜV SÜD	J03 Auditory active-implantable devices	Class III implantable

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

Devices exempted from the CECP are devices in scope of the CECP according to Art. 54(1) but for which the CECP was not applied by notified bodies due to exemption criteria under Art. 54(2).

NB number	NB	EMDN type - level 3	Risk class / type	Reason for CECP exemption
NB 0123	TÜV SÜD <sup>6</sup>	P07 Vascular and cardiac prostheses	Class III implantable	MDR Art. 54(2)b
NB 0123	TÜV SÜD	A05 Mechanical infusion systems, single-use	Class IIb ARMP	MDR Art. 54(2)b
NB 0123	TÜV SÜD	C01 Arterio-venous system devices	Class III implantable	MDR Art. 54(2)b
NB 0123	TÜV SÜD	A01 Arterio-venous system devices	Class III implantable	MDR Art. 54(2)b
NB 0123	TÜV SÜD	C01 Arterio-venous system devices	Class III implantable	MDR Art. 54(2)b
NB 0123	TÜV SÜD	H01 Surgical sutures	Class III implantable	MDR Art. 54(2)b
NB 0123	TÜV SÜD	H01 Surgical sutures	Class III implantable	MDR Art. 54(2)b
NB 0123	TÜV SÜD	H01 Surgical sutures	Class III implantable	MDR Art. 54(2)b
NB 0123	TÜV SÜD	H01 Surgical sutures	Class III implantable	MDR Art. 54(2)b
NB 0123	TÜV SÜD	H01 Surgical sutures	Class III implantable	MDR Art. 54(2)b
NB 0123	TÜV SÜD	H02 Mechanical surgical staplers	Class III implantable	MDR Art. 54(2)b
NB 0123	TÜV SÜD	H02 Mechanical surgical staplers	Class III implantable	MDR Art. 54(2)b
NB 0123	TÜV SÜD	H02 Mechanical surgical staplers	Class III implantable	MDR Art. 54(2)b
NB 0123	TÜV SÜD	H02 Mechanical surgical staplers	Class III implantable	MDR Art. 54(2)b

NB number	NB	EMDN type - level 3	Risk class / type	Reason for CECP exemption
NB 0123	TÜV SÜD	H03 Haemostasis clips	Class III implantable	MDR Art. 54(2)b
NB 0123	TÜV SÜD	H90 Suture devices - various	Class III implantable	MDR Art. 54(2)b
NB 0123	TÜV SÜD	J01 Cardiac functionality implantable devices	Class III implantable	MDR Art. 54(2)b
NB 0123	TÜV SÜD	J02 Implantable neurostimulators	Class III implantable	MDR Art. 54(2)b
NB 0123	TÜV SÜD	J02 Implantable neurostimulators	Class III implantable	MDR Art. 54(2)b
NB 0123	TÜV SÜD	J02 Implantable neurostimulators	Class III implantable	MDR Art. 54(2)b
NB 0123	TÜV SÜD	J04 Implantable pumps	Class III implantable	MDR Art. 54(2)b
NB 0123	TÜV SÜD	J04 Implantable pumps	Class III implantable	MDR Art. 54(2)b
NB 0123	TÜV SÜD	P07 Vascular and cardiac prostheses	Class III implantable	MDR Art. 54(2)b
NB 0123	TÜV SÜD	P07 Vascular and cardiac prostheses	Class III implantable	MDR Art. 54(2)b
NB 0123	TÜV SÜD	P07 Vascular and cardiac prostheses	Class III implantable	MDR Art. 54(2)b
NB 0123	TÜV SÜD	P07 Vascular and cardiac prostheses	Class III implantable	MDR Art. 54(2)b
NB 0123	TÜV SÜD	P07 Vascular and cardiac prostheses	Class III implantable	MDR Art. 54(2)b
NB 0123	TÜV SÜD	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 0123	TÜV SÜD	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 0123	TÜV SÜD	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 0123	TÜV SÜD	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament	Class III	MDR Art. 54(2)b

NB number	NB	EMDN type - level 3	Risk class / type	Reason for CECP exemption
		synthesis	implantable	
NB 0123	TÜV SÜD	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 0123	TÜV SÜD	P90 Implantable prosthetic and osteosynthesis devices - various	Class III implantable	MDR Art. 54(2)b
NB 0123	TÜV SÜD	P90 Implantable prosthetic and osteosynthesis devices - various	Class III implantable	MDR Art. 54(2)b
NB 0123	TÜV SÜD	P90 Implantable prosthetic and osteosynthesis devices - various	Class III implantable	MDR Art. 54(2)b
NB 0123	TÜV SÜD	P90 Implantable prosthetic and osteosynthesis devices - various	Class III implantable	MDR Art. 54(2)b
NB 0123	TÜV SÜD	P90 Implantable prosthetic and osteosynthesis devices - various	Class III implantable	MDR Art. 54(2)b
NB 0123	TÜV SÜD	P90 Implantable prosthetic and osteosynthesis devices - various	Class III implantable	MDR Art. 54(2)b
NB 0123	TÜV SÜD	Z12 Instruments for functional explorations and therapeutic interventions	Class IIb ARMP	MDR Art. 54(2)b
NB 0123	TÜV SÜD	Z12 Instruments for functional explorations and therapeutic interventions	Class IIb ARMP	MDR Art. 54(2)b
NB 0123	TÜV SÜD	Z12 Instruments for functional explorations and therapeutic interventions	Class IIb ARMP	MDR Art. 54(2)b
NB 0123	TÜV SÜD	Z12 Instruments for functional explorations and therapeutic interventions	Class IIb ARMP	MDR Art. 54(2)b
NB 0123	TÜV SÜD	Z12 Instruments for functional explorations and therapeutic interventions	Class IIb ARMP	MDR Art. 54(2)b
NB 0123	TÜV SÜD	Z12 Instruments for functional explorations and therapeutic interventions	Class IIb ARMP	MDR Art. 54(2)b
NB 0123	TÜV SÜD	Z12 Instruments for functional explorations and therapeutic interventions	Class IIb ARMP	MDR Art. 54(2)b

NB number	NB	EMDN type - level 3	Risk class / type	Reason for CECP exemption
		therapeutic interventions	ARMP	
NB 0123	TÜV SÜD	Z12 Instruments for functional explorations and therapeutic interventions	Class IIb ARMP	MDR Art. 54(2)b
NB 0124	DEKRA Certification GmbH	P07 Vascular and cardiac prostheses	Class III implantable	MDR Art. 54(2)b
NB 0197	TÜV Rheinland LGA Products GmbH	R90 Respiratory and anaesthesia devices - various	Class IIb ARMP	MDR Art. 54(2)b
NB 0297	DQS Medizinprodukte GmbH	A05 Mechanical infusion systems, single-use	Class IIb ARMP	MDR Art. 54(2)b
NB 0344	DEKRA Certification B.V.	P07 Vascular and cardiac prostheses	Class III implantable	MDR Art. 54(2)b
NB 0344	DEKRA Certification B.V.	C90 Cardiocirculatory devices - various	Class III implantable	MDR Art. 54(2)b
NB 0344	DEKRA Certification B.V.	P07 Vascular and cardiac prostheses	Class III implantable	MDR Art. 54(2)b
NB 0344	DEKRA Certification B.V.	P07 Vascular and cardiac prostheses	Class III implantable	MDR Art. 54(2)a
NB 0344	DEKRA Certification B.V.	P07 Vascular and cardiac prostheses	Class III implantable	MDR Art. 54(2)b
NB 0344	DEKRA Certification B.V.	P07 Vascular and cardiac prostheses	Class III implantable	MDR Art. 54(2)b
NB 0344	DEKRA Certification B.V.	P07 Vascular and cardiac prostheses	Class III implantable	MDR Art. 54(2)c
NB 0344	DEKRA Certification B.V.	Non declared	Class III implantable	MDR Art. 54(2)b
NB 0373	Istituto Superiore di Sanità	P90 Implantable prosthetic and osteosynthesis devices - various	Class III implantable	MDR Art. 54(2)b
NB 0373	Istituto Superiore di Sanità	P90 Implantable prosthetic and osteosynthesis devices - various	Class III implantable	MDR Art. 54(2)b
NB 0373	Istituto Superiore di Sanità	P90 Implantable prosthetic and osteosynthesis devices - various	Class III implantable	MDR Art. 54(2)b
NB 0373	Istituto Superiore di Sanità	P90 Implantable prosthetic and osteosynthesis devices - various	Class III implantable	MDR Art. 54(2)b

NB number	NB	EMDN type - level 3	Risk class / type	Reason for CECP exemption
NB 0373	Istituto Superiore di Sanità	P90 Implantable prosthetic and osteosynthesis devices - various	Class III implantable	MDR Art. 54(2)b
NB 0373	Istituto Superiore di Sanità	P90 Implantable prosthetic and osteosynthesis devices - various	Class III implantable	MDR Art. 54(2)b
NB 0373	Istituto Superiore di Sanità	P90 Implantable prosthetic and osteosynthesis devices - various	Class III implantable	MDR Art. 54(2)b
NB 0373	Istituto Superiore di Sanità	P90 Implantable prosthetic and osteosynthesis devices - various	Class III implantable	MDR Art. 54(2)b
NB 0373	Istituto Superiore di Sanità	P90 Implantable prosthetic and osteosynthesis devices - various	Class III implantable	MDR Art. 54(2)b
NB 0373	Istituto Superiore di Sanità	Q01 Dental devices	Class III implantable	MDR Art. 54(2)b
NB 0373	Istituto Superiore di Sanità	Q02 Ophthalmic devices	Class III implantable	MDR Art. 54(2)b
NB 0426	ITALCERT	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 0426	ITALCERT	Z12 Instruments for functional explorations and therapeutic interventions	Class IIb ARMP	MDR Art. 54(2)b
NB 0426	ITALCERT	Z12 Instruments for functional explorations and therapeutic interventions	Class IIb ARMP	MDR Art. 54(2)b
NB 0426	ITALCERT	Non declared	Class III implantable	MDR Art. 54(2)b
NB 0426	ITALCERT	Non declared	Class III implantable	MDR Art. 54(2)b
NB 0426	ITALCERT	Non declared	Class III implantable	MDR Art. 54(2)b
NB 0426	ITALCERT	Non declared	Class III implantable	MDR Art. 54(2)b
NB 0459	GMED SAS	H01 Surgical sutures	Class III implantable	MDR Art. 54(2)b
NB 0459	GMED SAS	H01 Surgical sutures	Class III implantable	MDR Art. 54(2)b
NB 0459	GMED SAS	H01 Surgical sutures	Class III implantable	MDR Art. 54(2)b

NB number	NB	EMDN type - level 3	Risk class / type	Reason for CECP exemption
NB 0459	GMED SAS	H01 Surgical sutures	Class III implantable	MDR Art. 54(2)b
NB 0459	GMED SAS	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 0459	GMED SAS	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 0459	GMED SAS	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 0459	GMED SAS	P90 Implantable prosthetic and osteosynthesis devices - various	Class III implantable	MDR Art. 54(2)b
NB 0459	GMED SAS	Z11 Bioimaging and radiotherapy instruments	Class IIb ARMP	MDR Art. 54(2)b
NB 0476	Kiwa Cermet Italia	Z12 Instruments for functional explorations and therapeutic interventions	Class IIb ARMP	MDR Art. 54(2)b
NB 0476	Kiwa Cermet Italia	Z12 Instruments for functional explorations and therapeutic interventions	Class IIb ARMP	MDR Art. 54(2)b
NB 0476	Kiwa Cermet Italia	Z12 Instruments for functional explorations and therapeutic interventions	Class IIb ARMP	MDR Art. 54(2)b
NB 0482	DNV MEDCERT GmbH	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 0482	DNV MEDCERT GmbH	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 0482	DNV MEDCERT GmbH	P07 Vascular and cardiac prostheses	Class III implantable	MDR Art. 54(2)b
NB 0482	DNV MEDCERT GmbH	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 0482	MEDCERT	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 0482	DNV MEDCERT GmbH	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b

NB number	NB	EMDN type - level 3	Risk class / type	Reason for CECP exemption
NB 0482	MEDCERT	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 0482	MEDCERT	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 0482	MEDCERT	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 0482	DNV MEDCERT GmbH	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 0482	DNV MEDCERT GmbH	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 0482	DNV MEDCERT GmbH	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 0482	MEDCERT	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 0482	MEDCERT	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 0482	DNV MEDCERT GmbH	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 0482	DNV MEDCERT GmbH	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 0482	DNV MEDCERT GmbH	Non declared	Class III implantable	MDR Art. 54(2)b
NB 0483	mdc medical device certification GmbH	C01 Arterio-venous system devices	Class III implantable	MDR Art. 54(2)b
NB 0483	mdc medical device certification	M04 Special dressings	Class III implantable	MDR Art. 54(2)b

NB number	NB	EMDN type - level 3	Risk class / type	Reason for CECP exemption
	GmbH			
NB 0483	mdc medical device certification GmbH	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 0483	mdc medical device certification GmbH	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 0483	mdc medical device certification GmbH	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 0483	mdc medical device certification GmbH	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 0483	mdc medical device certification GmbH	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 0483	mdc medical device certification GmbH	P90 Implantable prosthetic and osteosynthesis devices - various	Class III implantable	MDR Art. 54(2)b
NB 0483	mdc medical device certification GmbH	P90 Implantable prosthetic and osteosynthesis devices - various	Class III implantable	MDR Art. 54(2)b
NB 0483	mdc medical device certification GmbH	P90 Implantable prosthetic and osteosynthesis devices - various	Class III implantable	MDR Art. 54(2)b
NB 0483	mdc medical device certification GmbH	Q01 Dental devices	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI <sup>7</sup>	A01 Needles	Class III implantable	MDR Art. 54(2)a
NB 2797	BSI	C01 Arterio-venous system devices	Class III	MDR Art. 54(2)b

NB number	NB	EMDN type - level 3	Risk class / type	Reason for CECP exemption
			implantable	
NB 2797	BSI	C01 Arterio-venous system devices	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	C01 Arterio-venous system devices	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	C01 Arterio-venous system devices	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	C01 Arterio-venous system devices	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	C01 Arterio-venous system devices	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	C01 Arterio-venous system devices	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	C01 Arterio-venous system devices	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	C01 Arterio-venous system devices	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	C01 Arterio-venous system devices	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	C03 Cardiac surgery and heart transplant devices	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	C90 Cardiocirculatory devices - various	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	F90 Dialysis devices - various	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	F90 Dialysis devices - various	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	F90 Dialysis devices - various	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	F90 Dialysis devices - various	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	F90 Dialysis devices - various	Class III implantable	MDR Art. 54(2)b

NB number	NB	EMDN type - level 3	Risk class / type	Reason for CECP exemption
NB 2797	BSI	F90 Dialysis devices - various	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	F90 Dialysis devices - various	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	F90 Dialysis devices - various	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	F90 Dialysis devices - various	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	F90 Dialysis devices - various	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	F90 Dialysis devices - various	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	H01 Surgical sutures	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	H01 Surgical sutures	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	H01 Surgical sutures	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	H01 Surgical sutures	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	H01 Surgical sutures	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	H01 Surgical sutures	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	H01 Surgical sutures	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	H01 Surgical sutures	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	H01 Surgical sutures	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	H01 Surgical sutures	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	H01 Surgical sutures	Class III	MDR Art. 54(2)b

NB number	NB	EMDN type - level 3	Risk class / type	Reason for CECP exemption
			implantable	
NB 2797	BSI	H01 Surgical sutures	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	H01 Surgical sutures	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	H01 Surgical sutures	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	H01 Surgical sutures	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	H01 Surgical sutures	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	H01 Surgical sutures	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	H01 Surgical sutures	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	H01 Surgical sutures	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	H03 Haemostasis clips	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	H03 Haemostasis clips	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	H90 Suture devices - various	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	H90 Suture devices - various	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	H90 Suture devices - various	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	H90 Suture devices - various	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	J01 Cardiac functionality implantable devices	Class III implantable	MDR Art. 54(2)b

NB number	NB	EMDN type - level 3	Risk class / type	Reason for CECP exemption
NB 2797	BSI	J01 Cardiac functionality implantable devices	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	J01 Cardiac functionality implantable devices	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	J02 Implantable neurostimulators	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	J02 Implantable neurostimulators	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	J02 Implantable neurostimulators	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	J04 Implantable pumps	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	M04 Special dressings	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	N01 Encephalic and peripheral nervous system devices	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P01 Facial and odontological prostheses	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P06 Breast implants	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P06 Breast implants	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P06 Breast implants	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P07 Vascular and cardiac prostheses	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P07 Vascular and cardiac prostheses	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P07 Vascular and cardiac prostheses	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P07 Vascular and cardiac prostheses	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P07 Vascular and cardiac prostheses	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P07 Vascular and cardiac prostheses	Class III	MDR Art. 54(2)b

NB number	NB	EMDN type - level 3	Risk class / type	Reason for CECP exemption
			implantable	
NB 2797	BSI	P07 Vascular and cardiac prostheses	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P07 Vascular and cardiac prostheses	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P07 Vascular and cardiac prostheses	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P07 Vascular and cardiac prostheses	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P07 Vascular and cardiac prostheses	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P07 Vascular and cardiac prostheses	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P07 Vascular and cardiac prostheses	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P07 Vascular and cardiac prostheses	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P07 Vascular and cardiac prostheses	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P07 Vascular and cardiac prostheses	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P07 Vascular and cardiac prostheses	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P07 Vascular and cardiac prostheses	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P07 Vascular and cardiac prostheses	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P07 Vascular and cardiac prostheses	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P07 Vascular and cardiac prostheses	Class III implantable	MDR Art. 54(2)b

NB number	NB	EMDN type - level 3	Risk class / type	Reason for CECP exemption
NB 2797	BSI	P07 Vascular and cardiac prostheses	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b

NB number	NB	EMDN type - level 3	Risk class / type	Reason for CECP exemption
NB 2797	BSI	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b

NB number	NB	EMDN type - level 3	Risk class / type	Reason for CECP exemption
NB 2797	BSI	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b

NB number	NB	EMDN type - level 3	Risk class / type	Reason for CECP exemption
NB 2797	BSI	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b

NB number	NB	EMDN type - level 3	Risk class / type	Reason for CECP exemption
NB 2797	BSI	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b

NB number	NB	EMDN type - level 3	Risk class / type	Reason for CECP exemption
NB 2797	BSI	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P09 Orthopaedic prostheses, osteosynthesis devices, devices for tendon and ligament synthesis	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P90 Implantable prosthetic and osteosynthesis devices - various	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P90 Implantable prosthetic and osteosynthesis devices - various	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P90 Implantable prosthetic and osteosynthesis devices - various	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P90 Implantable prosthetic and osteosynthesis devices - various	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P90 Implantable prosthetic and osteosynthesis devices - various	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P90 Implantable prosthetic and osteosynthesis devices - various	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P90 Implantable prosthetic and osteosynthesis devices - various	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P90 Implantable prosthetic and osteosynthesis devices - various	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P90 Implantable prosthetic and osteosynthesis devices - various	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P90 Implantable prosthetic and osteosynthesis devices - various	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P90 Implantable prosthetic and osteosynthesis devices - various	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P90 Implantable prosthetic and osteosynthesis devices - various	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P90 Implantable prosthetic and osteosynthesis devices - various	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P90 Implantable prosthetic and osteosynthesis devices - various	Class III implantable	MDR Art. 54(2)b

NB number	NB	EMDN type - level 3	Risk class / type	Reason for CECP exemption
NB 2797	BSI	P90 Implantable prosthetic and osteosynthesis devices - various	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P90 Implantable prosthetic and osteosynthesis devices - various	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P90 Implantable prosthetic and osteosynthesis devices - various	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P90 Implantable prosthetic and osteosynthesis devices - various	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P90 Implantable prosthetic and osteosynthesis devices - various	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P90 Implantable prosthetic and osteosynthesis devices - various	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P90 Implantable prosthetic and osteosynthesis devices - various	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P90 Implantable prosthetic and osteosynthesis devices - various	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	P90 Implantable prosthetic and osteosynthesis devices - various	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	Q01 Dental devices	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	Q01 Dental devices	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	Q01 Dental devices	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	Q01 Dental devices	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	U07 Devices for the treatment of incontinence	Class III implantable	MDR Art. 54(2)b
NB 2797	BSI	Z11 Bioimaging and radiotherapy instruments	Class IIb ARMP	MDR Art. 54(2)b
NB 2797	BSI	Z11 Bioimaging and radiotherapy instruments	Class IIb ARMP	MDR Art. 54(2)b
NB 2797	BSI	Z11 Bioimaging and radiotherapy instruments	Class IIb ARMP	MDR Art. 54(2)b
NB 2797	BSI	Z12 Instruments for functional explorations and	Class IIb	MDR Art. 54(2)b

NB number	NB	EMDN type - level 3	Risk class / type	Reason for CECP exemption
		therapeutic interventions	ARMP	
NB 2797	BSI	Z12 Instruments for functional explorations and therapeutic interventions	Class IIb ARMP	MDR Art. 54(2)b
NB 2797	BSI	Z12 Instruments for functional explorations and therapeutic interventions	Class IIb ARMP	MDR Art. 54(2)b
NB 2797	BSI	Z12 Instruments for functional explorations and therapeutic interventions	Class IIb ARMP	MDR Art. 54(2)b
NB 2797	BSI	Z12 Instruments for functional explorations and therapeutic interventions	Class IIb ARMP	MDR Art. 54(2)b
NB 2797	BSI	Z12 Instruments for functional explorations and therapeutic interventions	Class IIb ARMP	MDR Art. 54(2)b
NB 2797	BSI	Z12 Instruments for functional explorations and therapeutic interventions	Class IIb ARMP	MDR Art. 54(2)b
NB 2797	BSI	Z12 Instruments for functional explorations and therapeutic interventions	Class IIb ARMP	MDR Art. 54(2)b
NB 2797	BSI	Z12 Instruments for functional explorations and therapeutic interventions	Class IIb ARMP	MDR Art. 54(2)b