Anexa nr. 1
La Procedurile administrative pentru notificarea dispozitivelor medicale care deţin marcajul CE

Către Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. __ din __.__.2023

Solicitantul SC "Denolga Medical" SRL, cu sediul mun. Chișinău, str. Grenoble, 149A, tel/fax: +373 22 260-602, +373 22 260-601, e-mail: olesea.cucerenco@yahoo.com,
solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii şi tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

Se anexează următoarele acte:

Conform Anexei nr. 3

EC-Declaration of Conformity, KARL STORZ DE & Co. KG, Germania, 3 file/ buc.
Lista dispozitivelor medicale (versiunea Excel);
Notified Body Confirmation Letter, KARL STORZ DE & Co. KG, Germania, 67 file/ buc.

Data __.__.2023 Semnătura _____

Tabelul de recepționare a notificării

(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	Digitally signed by Gherman Irina Date: 2023.09.22 11:56:38 EEST Reason: MoldSign Signature Location: Moldova
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

Anexa nr. 2
La Procedurile administrative pentru notificarea dispozitivelor medicale care deţin marcajul CE

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAŢIE PE PROPRIE RĂSPUNDERE

Solicitant: **SC „Denolga Medical" SRL**, cu sediul mun. Chișinău, str. Grenoble 149A,

declar pe proprie răspundere, cunoscând prevederile art. **352[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declaraţii, că documentele și datele furnizate pentru notificarea dispozitivului medical:

Conform Anexei nr. 3

Sunt autentice și corespund realității.

Cucerenco Olesea, jurisconsult
Numele, prenumele şi funcţia *Semnătura*

_____

Data __.__.2023

KARL STORZ — ENDOSKOPE

EC-DECLARATION OF CONFORMITY

EG-KONFORMITÄTSERKLÄRUNG

Device Name Produkt Name	Foreign Body Forceps, 9 Fr.
Model Number(s) Modell Nummer(n)	27175B
Classification Klassifizierung	Class I per Annex IX, Rule 6 of Council Directive 93/42/EEC Klasse I gemäß Anhang IX, Regel 6 der Richtlinie 93/42/EWG des Rates

We issue the present Declaration of Conformity on our sole responsibility and herewith declare self-dependent that the device mentioned above meets the Essential Requirements as defined in Annex I MDD 93/42/EEC.
Wir stellen die vorliegend Konformitätserklärung in Eigenverantwortung aus und erklären hiermit unter alleiniger Verantwortung, dass das oben genannte Produkt die Grundlegenden Anforderungen gemäß Anhang I MDD 93/42/EWG erfüllt.

This Declaration of Conformity is issued according to Annex VII Council Directive 93/42/EEC for Medical Devices *(for class I devices).*
Diese Konformitätserklärung ist erstellt gemäß Anhang VII Richtlinie 93/42/EWG des Rates über Medizinprodukte *(für Klasse I Produkte).*

Full list of applied standards, directives and laws (12-C2.3.F013-LOAS-CM001) on request.
Vollständige Liste angewandter Normen, Richtlinien und Gesetze (12-C2.3.F013-LOAS-CM001) auf Anfrage.

This Declaration is valid until: 2023-07-16
Diese Erklärung ist gültig bis: 2023-07-16

CE

KARL STORZ SE & Co. KG
Dr.-Karl-Storz-Straße 34
78532 Tuttlingen
Germany

Tuttlingen, 17 Juli 2018

i. V. Serkan Sezer
Vice President
Global Quality Management,
Regulatory Affairs, RSB & Service

This declaration loses all validity if KARL STORZ SE & Co. KG performs a product change which affects the Conformance to the Essential Requirements or an alteration of any kind not approved by KARL STORZ SE & Co. KG was made at the device mentioned above.
Diese Erklärung verliert ihre Gültigkeit sobald KARL STORZ SE & Co. KG Produktänderungen durchführt, welche die Konformität mit den Grundlegenden Anforderungen beeinflusst oder eine Änderung jeglicher Art ohne Freigabe durch die KARL STORZ SE & Co. KG am oben genannten Produkt durchgeführt wird.

KARL STORZ — ENDOSKOPE

EC-DECLARATION OF CONFORMITY

EG-KONFORMITÄTSERKLÄRUNG

Device Name Produkt Name	Biopsy Forceps, 7 Fr., 40 cm
Model Number(s) Modell Nummer(n)	27177A
Classification Klassifizierung	Class I per Annex IX, Rule 6 of Council Directive 93/42/EEC Klasse I gemäß Anhang IX, Regel 6 der Richtlinie 93/42/EWG des Rates

We issue the present Declaration of Conformity on our sole responsibility and herewith declare self-dependent that the device mentioned above meets the Essential Requirements as defined in Annex I MDD 93/42/EEC.
Wir stellen die vorliegend Konformitätserklärung in Eigenverantwortung aus und erklären hiermit unter alleiniger Verantwortung, dass das oben genannte Produkt die Grundlegenden Anforderungen gemäß Anhang I MDD 93/42/EWG erfüllt.

This Declaration of Conformity is issued according to Annex VII Council Directive 93/42/EEC for Medical Devices *(for class I devices).*
Diese Konformitätserklärung ist erstellt gemäß Anhang VII Richtlinie 93/42/EWG des Rates über Medizinprodukte *(für Klasse I Produkte).*

Full list of applied standards, directives and laws (12-C2.3.F013-LOAS-CM001) on request.
Vollständige Liste angewandter Normen, Richtlinien und Gesetze (12-C2.3.F013-LOAS-CM001) auf Anfrage.

This Declaration is valid until: 2023-07-16
Diese Erklärung ist gültig bis: 2023-07-16

CE

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Dr.-Karl-Storz-Straße 34
78532 Tuttlingen
Germany

Tuttlingen, 17 Juli 2018

i. V. Serkan Sezer
Vice President
Global Quality Management,
Regulatory Affairs, RSB & Service

This declaration loses all validity if KARL STORZ SE & Co. KG performs a product change which affects the Conformance to the Essential Requirements or an alteration of any kind not approved by KARL STORZ SE & Co. KG was made at the device mentioned above.
Diese Erklärung verliert ihre Gültigkeit sobald KARL STORZ SE & Co. KG Produktänderungen durchführt, welche die Konformität mit den Grundlegenden Anforderungen beeinflusst oder eine Änderung jeglicher Art ohne Freigabe durch die KARL STORZ SE & Co. KG am oben genannten Produkt durchgeführt wird.

KARL STORZ — ENDOSKOPE

EC-DECLARATION OF CONFORMITY

EG-KONFORMITÄTSERKLÄRUNG

Device Name Produkt Name	Biopsy Forceps, 9 Fr., 40 cm
Model Number(s) Modell Nummer(n)	27177B
Classification Klassifizierung	Class I per Annex IX, Rule 6 of Council Directive 93/42/EEC Klasse I gemäß Anhang IX, Regel 6 der Richtlinie 93/42/EWG des Rates

We issue the present Declaration of Conformity on our sole responsibility and herewith declare self-dependent that the device mentioned above meets the Essential Requirements as defined in Annex I MDD 93/42/EEC.
Wir stellen die vorliegend Konformitätserklärung in Eigenverantwortung aus und erklären hiermit unter alleiniger Verantwortung, dass das oben genannte Produkt die Grundlegenden Anforderungen gemäß Anhang I MDD 93/42/EWG erfüllt.

This Declaration of Conformity is issued according to Annex VII Council Directive 93/42/EEC for Medical Devices *(for class I devices).*
Diese Konformitätserklärung ist erstellt gemäß Anhang VII Richtlinie 93/42/EWG des Rates über Medizinprodukte *(für Klasse I Produkte).*

Full list of applied standards, directives and laws (12-C2.3.F013-LOAS-CM001) on request.
Vollständige Liste angewandter Normen, Richtlinien und Gesetze (12-C2.3.F013-LOAS-CM001) auf Anfrage.

This Declaration is valid until: 2023-07-16
Diese Erklärung ist gültig bis: 2023-07-16

CE

KARL STORZ SE & Co. KG
Dr.-Karl-Storz-Straße 34
78532 Tuttlingen
Germany

Tuttlingen, 17 Juli 2018

i. V. Serkan Sezer
Vice President
Global Quality Management,
Regulatory Affairs, RSB & Service

This declaration loses all validity if KARL STORZ SE & Co. KG performs a product change which affects the Conformance to the Essential Requirements or an alteration of any kind not approved by KARL STORZ SE & Co. KG was made at the device mentioned above.
Diese Erklärung verliert ihre Gültigkeit sobald KARL STORZ SE & Co. KG Produktänderungen durchführt, welche die Konformität mit den Grundlegenden Anforderungen beeinflusst oder eine Änderung jeglicher Art ohne Freigabe durch die KARL STORZ SE & Co. KG am oben genannten Produkt durchgeführt wird.

TÜV SÜD Product Service GmbH · Ridlerstraße 65 · 80339 München · Deutschland

KARL STORZ SE & Co. KG
Dr.-Karl-Storz-Straße 34
78532 Tuttlingen
Germany

Product Service

Mehr Wert.
Mehr Vertrauen.

Your Ref/Name	Our Ref/Name	Tel. /E-Mail	Fax	Date	Page
84462_2023_06_MDD	713300646-1 ID 2023-236	+49 89 50084-652 marie-astrid.viard@tuvsud.com	n.a.	28. June 2023	1 von 66

Notified Body Confirmation Letter

Reference: 713300646-1

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that, TÜV SÜD Product Service GmbH, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0123 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer.

KARL STORZ SE & Co. KG
Dr.-Karl-Storz-Straße 34
78532 Tuttlingen
Germany

SRN Number: DE-MF-000005723

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below, see attachment:

- Table 1 identifies the devices which an MDR application has been received, written agreement concluded and for which the TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive.
- Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the TÜV SÜD Product Service GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that:

- the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or
- provided evidence that a competent authority of a Member State had granted a derogation in accordance with Article 59(1) of the MDR or
- provided evidence that a competent authority of a Member State had granted an exemption from the applicable conformity assessment procedure in accordance with Article 97(1) of the MDR respectively,

by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by EU 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,

TÜV SÜD Product Service GmbH
Medical and Health Services

Signatur:

E-Mail: Marie-Astrid.Viard@tuvsud.com

Marie-Astrid Viard
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Signatur: Hoyer Julia
Hoyer Julia (28. Juni 2023 17:55 GMT+2)

E-Mail: Julia.Hoyer@tuvsud.com

Julia Hoyer
Head of Certification Body - Deputy

Product Service

ATTACHMENT

Table 1: Devices covered by this letter and for which the TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Accessories for Insufflators	☐N/A or ☐ Class IIb implantable non-WET device ☒ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or ☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Active controlling systems, components of software (SCB)	☐N/A or ☐ Class IIb implantable non-WET device ☒ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or ☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
			Evidence #1; CA# Evidence #2; CA#
EM Navigation	☐N/A or ☐ Class IIb implantable non-WET device ☒ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or ☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Foot Switch for Laser	☐N/A or ☐ Class IIb implantable non-WET device ☒ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or ☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Foot Switches for Motor Control Unit	☐N/A or ☐ Class IIb implantable non-WET device ☒ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or ☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Foot Switches for Pumps	☐N/A or ☐ Class IIb implantable non-WET device ☒ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or ☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
HF Instruments with movable jaws	☐N/A or	☒ N/A or	☐ N/A or

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class IIb implantable non-WET device ☒ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☐ Identification of the corresponding device under MDD/AIMDD	☒ Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or ☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
HF Instruments without movable jaws/ HF Electrodes	☐N/A or ☐ Class IIb implantable non-WET device ☒ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or ☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
HF Suction/ Irrigation Instruments	☐N/A or ☐ Class IIb implantable non-WET device	☒ N/A or	☐ N/A or ☒ Certification as follows:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☒ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☐ Identification of the corresponding device under MDD/AIMDD	Certificate #: G1 084462 0012 Rev.01; NB # 0123 or ☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
HF Generators	☐N/A or ☐ Class IIb implantable non-WET device ☒ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or ☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
HF Foot Switches	☐N/A or ☐ Class IIb implantable non-WET device ☒ Class IIb excluding Class IIb implantable non-WET	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device		or ☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
HF Working Elements / working inserts	☐N/A or ☐ Class IIb implantable non-WET device ☒ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or ☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Insufflators	☐N/A or ☐ Class IIb implantable non-WET device ☒ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device		☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Laser Devices	☐N/A or ☐ Class IIb implantable non-WET device ☒ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or ☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Lithotripsy Probes	☐N/A or ☐ Class IIb implantable non-WET device ☒ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device		☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Suction/ Irrigation Pumps	☐N/A or ☐ Class IIb implantable non-WET device ☒ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or ☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Tubing Sets Insufflators	☐N/A or ☐ Class IIb implantable non-WET device ☒ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device		☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Cannulas	☐N/A or ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☒ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or ☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Instruments with movable jaws	☐N/A or ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☒ Class IIa ☐ Class I devices placed on the market in sterile condition	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device		☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Instruments without movable jaws	☐N/A or ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☒ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or ☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
ENT Balloon Catheter	☐N/A or ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☒ Class IIa ☐ Class I devices placed on the market in sterile condition	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device		☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Fiberscopes with channel	☐N/A or ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☒ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or ☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Fiberscopes without channel	☐N/A or ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☒ Class IIa ☐ Class I devices placed on the market in sterile condition	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device		☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Flexible Videoscopes with channel	☐N/A or ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☒ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or ☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Flexible Videoscopes without channel	☐N/A or ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☒ Class IIa ☐ Class I devices placed on the market in sterile condition	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device		☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Laser Fibers	☐N/A or ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☒ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or ☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Light Carrier (adaptable)	☐N/A or ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☒ Class IIa ☐ Class I devices placed on the market in sterile condition	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device		☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Light Sources	☐N/A or ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☒ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or ☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Handpieces/ Motors	☐N/A or ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☒ Class IIa ☐ Class I devices placed on the market in sterile condition	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device		☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Morcellator blades	☐N/A or ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☒ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or ☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Morcellator handpieces	☐N/A or ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☒ Class IIa ☐ Class I devices placed on the market in sterile condition	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device		☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Motor Control Unit	☐N/A or ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☒ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or ☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Optics (Telescopes) with channel	☐N/A or ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☒ Class IIa ☐ Class I devices placed on the market in sterile condition	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device		☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Optics (Telescopes) without channel	☐N/A or ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☒ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or ☐ N/A - Device did not require a Notified Body certificate under Directives
Rigid Videoscopes with channel	☐N/A or ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☒ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or ☐ N/A - Device did not require a Notified Body certificate under Directives

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class III implantable custom-made device		
Rigid Videoscopes without channel	☐N/A or ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☒ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or ☐ N/A - Device did not require a Notified Body certificate under Directives
Semiflexible endoscopes with channel	☐N/A or ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☒ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or ☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Shaver/ Drills	☐N/A or ☐ Class IIb implantable non-WET device	☒ N/A or	☐ N/A or ☒ Certification as follows:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class IIb excluding Class IIb implantable non-WET ☒ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☐ Identification of the corresponding device under MDD/AIMDD	Certificate #: G1 084462 0012 Rev.01; NB # 0123 or ☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Sheaths	☐N/A or ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☒ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or ☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Suction/ Irrigation Instruments	☐N/A or ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☒ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device		or ☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Trocars	☐N/A or ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☒ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or ☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Working Elements/ Working Inserts	☐N/A or ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☒ Class IIa ☐ Class I devices placed on the market in sterile condition	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device		☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Adhesive bandage	☐N/A or ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☒ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: G2S 084462 0013 Rev.01; NB # 0123 or ☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Covers	☐N/A or ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☒ Class I devices placed on the market in sterile condition	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: G2S 084462 0013 Rev.01; NB # 0123 or

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device		☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Covers for Touchscreen	☐N/A or ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☒ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: G2S 084462 0013 Rev.01; NB # 0123 or ☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Covers for camera	☐N/A or ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☒ Class I devices placed on the market in sterile condition	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: G2S 084462 0013 Rev.01; NB # 0123 or

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device		☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Surgical plume evacuation system filter	☐N/A or ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☒ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: G2S 084462 0013 Rev.01; NB # 0123 or ☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Guide probes	☐N/A or ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☒ Class I devices placed on the market in sterile condition	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: G2S 084462 0013 Rev.01; NB # 0123 or

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device		☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Surgical irrigation/aspiration tubing sets	☐N/A or ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☒ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: G2S 084462 0013 Rev.01; NB # 0123 or ☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Surgical irrigation/aspiration handles	☐N/A or ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☒ Class I devices placed on the market in sterile condition	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: G2S 084462 0013 Rev.01; NB # 0123 or

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device		☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Optic stoppers	☐N/A or ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☒ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: G2S 084462 0013 Rev.01; NB # 0123 or ☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Spray catheters	☐N/A or ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☒ Class I devices placed on the market in sterile condition	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: G2S 084462 0013 Rev.01; NB # 0123 or

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device		☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Trocar valves	☐N/A or ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☒ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: G2S 084462 0013 Rev.01; NB # 0123 or ☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Valve seals	☐N/A or ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☒ Class I devices placed on the market in sterile condition	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: G2S 084462 0013 Rev.01; NB # 0123 or

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device		☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#

Table 2: Devices covered by this letter and for which the TÜV SÜD Product Service GmbH is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Adenotom	☐ N/A or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☐ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☐ N/A or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or ☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Applicator	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☐ N/A or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or ☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA#

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
			Evidence #2; CA#
Artery clamp	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☐ N/A or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or ☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Barrel catcher	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☐ N/A or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or ☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Biopsy forceps	☒ N/A	☒ N/A	☐ N/A

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	or ☐ Identification of the corresponding device under MDD/AIMDD:	or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or ☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Biopsy scoop	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☐ N/A or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or ☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Blades	☒ N/A or	☒ N/A or	☐ N/A or

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☐ Identification of the corresponding device under MDD/AIMDD:	☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or ☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Bone file	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☐ N/A or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or ☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Bone shrapnel	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☐ N/A or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device		or ☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Bougie-Urethrotom	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☐ N/A or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or ☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Brushes	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☐ N/A or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device		☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Cement applicator	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☐ N/A or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or ☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Chisel	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☐ N/A or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or ☒ N/A - Device did not require a Notified Body certificate under Directives

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device		or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Clamps	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☐ N/A or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or ☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Conchotom	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☐ N/A or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or ☒ N/A - Device did not require a Notified Body certificate under Directives or

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device		☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Curette	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☐ N/A or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or ☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Dilatation mandrel	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☐ N/A or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or ☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
			had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Dilation sets	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☐ N/A or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or ☒ N/A - Device did not require a Notified Body certificate under Directives
Dilation sleeve	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☐ N/A or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or ☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Dilators	☒ N/A	☒ N/A	☐ N/A

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	or ☐ Identification of the corresponding device under MDD/AIMDD:	or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or ☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Dissectors	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☐ N/A or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or ☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Elevator	☒ N/A or ☐ Class III	☒ N/A or	☐ N/A or ☐ Certification as follows:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☐ Identification of the corresponding device under MDD/AIMDD:	Certificate #1; NB #: Certificate #2; NB #: or ☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Endotom	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☐ N/A or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or ☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Extractor	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☐ N/A or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device		or ☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Fixation instruments	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☐ N/A or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or ☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Footplate hooks	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☐ N/A or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device		☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Forceps	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☐ N/A or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or ☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Gripper	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☐ N/A or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or ☒ N/A - Device did not require a Notified Body certificate under Directives

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device		or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Guide probes	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☐ N/A or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or ☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Guide sleeves	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☐ N/A or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or ☒ N/A - Device did not require a Notified Body certificate under Directives or

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device		☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Guide wire	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☐ N/A or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or ☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Hollow milling cutter	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☐ N/A or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or ☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
			had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Hooks	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☐ N/A or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or ☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Injection cannula	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☐ N/A or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or ☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA#

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
			Evidence #2; CA#
Insert Femoral Targeting Device	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☐ N/A or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or ☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Knives	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☐ N/A or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or ☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Lock cap	☒ N/A	☒ N/A	☐ N/A

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	or ☐ Identification of the corresponding device under MDD/AIMDD:	or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or ☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Mandrel	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☐ N/A or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or ☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Measuring cylinder	☒ N/A or	☒ N/A or	☐ N/A or

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☐ Identification of the corresponding device under MDD/AIMDD:	☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or ☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Micro fork	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☐ N/A or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or ☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Needle	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☐ N/A or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device		or ☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Needle holder	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☐ N/A or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or ☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Obturator	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☐ N/A or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device		☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Osteotome	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☐ N/A or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or ☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Outer cannula	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☐ N/A or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or ☒ N/A - Device did not require a Notified Body certificate under Directives

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device		or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Outer sheath	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☐ N/A or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or ☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Patellar sawing template	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☐ N/A or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or ☒ N/A - Device did not require a Notified Body certificate under Directives or

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device		☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Perforator	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☐ N/A or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or ☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Plunger	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☐ N/A or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or ☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
			had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Probe	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☐ N/A or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or ☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Punching instruments	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☐ N/A or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or ☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA#

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
			Evidence #2; CA#
Puncture needle	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☐ N/A or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or ☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Pylorotome	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☐ N/A or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or ☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Raspatorium	☒ N/A	☒ N/A	☐ N/A

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	or ☐ Identification of the corresponding device under MDD/AIMDD:	or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or ☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Rasp	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☐ N/A or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or ☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Retactor	☒ N/A or	☒ N/A or	☐ N/A or

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☐ Identification of the corresponding device under MDD/AIMDD:	☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or ☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Saw	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☐ N/A or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or ☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Scalpel handle	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☐ N/A or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device		or ☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Scissors	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☐ N/A or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or ☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Screw driver	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☐ N/A or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device		☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Seaming instrument	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☐ N/A or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or ☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Self-retaining retractor	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☐ N/A or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or ☒ N/A - Device did not require a Notified Body certificate under Directives

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device		or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Sleeves	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☐ N/A or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or ☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Speculum	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☐ N/A or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or ☒ N/A - Device did not require a Notified Body certificate under Directives or

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device		☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Spoon	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☐ N/A or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or ☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Tampon thongs	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☐ N/A or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or ☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
			had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Tap	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☐ N/A or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or ☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Tendon strength tester	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☐ N/A or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or ☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA#

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
			Evidence #2; CA#
Thread clamps	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☐ N/A or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or ☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Thread guide	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☐ N/A or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or ☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Thread hook	☒ N/A	☒ N/A	☐ N/A

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	or ☐ Identification of the corresponding device under MDD/AIMDD:	or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or ☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Thread scissors	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☐ N/A or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or ☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Thread forceps	☒ N/A or	☒ N/A or	☐ N/A or

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☐ Identification of the corresponding device under MDD/AIMDD:	☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or ☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Trepan	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☐ N/A or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or ☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Trocar	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☐ N/A or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device		or ☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Valves	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☐ N/A or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or ☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Work inserts	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☐ N/A or ☐ Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device		☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#

Confirmation Letter Version History

Date	NB internal reference traceable to each version of the letter	Action
2023-06-27	713300646-1	Initial letter
2023-06-28	713300646-1	Correction of certificate for class Is devices

Anexa nr. 3

Nr.	Numărul de catalog (referință)*	Denumire generică (denumirea dispozitivului)	Denumire comercială (brand)*	Modelul	Cod GMDN*	
1	27175B	Foreign Body Forceps, 9 Fr.	Karl Storz	27175B	37100	I
2	27177A	Biopsy Forceps, 7 Fr., 40 cm	Karl Storz	27177A	11775	I
3	27177B	Biopsy Forceps, 9 Fr., 40 cm	Karl Storz	27177B	11775	I