Manufacturer's Declaration

in relation to Regulation 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, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Temena GmbH
Manufacturer address and contact details	Mittelhöfer Str. 1, D-34587 Felsberg
Single Registration Number (SRN) (if available)	DE-MF-000005111

Authorised Representative name (if applicable)	-
Authorised Representative address and contact details	-
Single Registration Number (SRN) (if available)	-

Notified body name (if applicable)	☒ See attached schedule
Notified body number (if applicable)	☒ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	☒ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	☒ See attached schedule
End date of extended validity/transition period	☒ See attached schedule

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021, was/were not withdrawn by 20 March 2023
- *Choose applicable statements:*

☐ Expired *before* 20 March 2023:

☐ Before the original date of expiry as indicated on the Directive Certificate, we and the notified body have signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment in respect of the device covered by the expired certificate or in respect of a device intended to substitute that device

☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request)

☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

☐ Expired/expires *after* 20 March 2023:

☒ A formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its substitute and a signed written agreement is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

➢ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

☐ A formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its substitute and a signed written agreement is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

- *Choose one applicable statement:*

☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

☒ A QMS in accordance with Article 10(9) MDR is in place.

☒ A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- The device(s) has/have not been significantly changed in its/their design and intended purpose since 26 May 2021.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Temena GmbH

Felsberg, June 13th, 2023

Monica Waskönig

Temena
TEMENA GmbH
Mittelhöfer Straße1
34587 FELSBERG - DEUTSCHLAND
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Monica Waskönig

CEO

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate prior to the extension of the validity** (if applicable)	**Notified Body name and number**	**End date of extended validity/transition period**	**Substitute Device** (if applicable)
Stimulation UPA					
02050-22.1 UPA 50 22Gx50mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
02070-22.1 UPA 70 22Gx70mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
02090-21.1 UPA 90 21Gx90mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
02025-24 UPA 25 24Gx25mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
02050-23 UPA 50 23Gx50mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
02070-23 UPA 70 23Gx70mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
02050-22 UPA 50 22Gx50mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
02070-22 UPA 70 22Gx70mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
02090-22 UPA 90 22Gx90mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
02090-21 UPA 90 21Gx90mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
02150-21 UPA 150 21Gx150mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
902050-22.1 UPA 50 22Gx50mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
902070-22.1 UPA 70 22Gx70mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
902090-21.1 UPA 90 21Gx90mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
902025-24 UPA 25 24Gx25mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.

902050-23 UPA 50 23Gx50mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
902070-23 UPA 70 23Gx70mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
902050-22 UPA 50 22Gx50mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
902070-22 UPA 70 22Gx70mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
902090-22 UPA 90 22Gx90mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
902090-21 UPA 90 21Gx90mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
902150-21 UPA 150 21Gx150mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
Stimulation UPB					
83050-22.1 UPB 50 22Gx50mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
83070-22.1 UPB 70 22Gx70mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
83090-21.1 UPB 90 21Gx90mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
83100-21.1 UPB 100 21Gx100mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
83025-24 UPB 25 24Gx25mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
83035-24 UPB 35 24Gx35mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
83030-22 UPB 30 22Gx30mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
83050-22 UPB 50 22Gx50mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
83070-22 UPB 70 22Gx70mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
83090-21 UPB 90 21Gx90mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
83100-21 UPB 100 21Gx100mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
83120-21 UPB 120 21Gx120mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
83150-21 UPB 150 21Gx150mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
983050-22.1 UPB 50 22Gx50mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.

983070-22.1 UPB 70 22Gx70mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
983090-21.1 UPB 90 21Gx90mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
983100-21.1 UPB 100 21Gx100mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
983025-24 UPB 25 24Gx25mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
983035-24 UPB 35 24Gx35mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
983030-22 UPB 30 22Gx30mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
983050-22 UPB 50 22Gx50mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
983070-22 UPB 70 22Gx70mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
983090-21 UPB 90 21Gx90mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
983100-21 UPB 100 21Gx100mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
983120-21 UPB 120 21Gx120mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
983150-21 UPB 150 21Gx150mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
Stimulation UPC					
92050-22.1 UPC 50 22Gx50mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
92070-22.1 UPC 70 22Gx70mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
92090-21.1 UPC 90 21Gx90mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
92025-24 UPC 25 24Gx25mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
92035-24 UPC 35 24Gx35mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
92050-23 UPC 50 23Gx50mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
92050-22 UPC 50 22Gx50mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
92090-22 UPC 90 22Gx90mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
92070-23 UPC 70 23Gx70mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.

92070-22 UPC 70 22Gx70mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
92090-21 UPC 90 21Gx90mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
92100-21 UPC 100 21Gx100mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
92120-21 UPC 120 21Gx120mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
92150-21 UPC 150 21Gx150mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
992050-22.1 UPC 50 22Gx50mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
992070-22.1 UPC 70 22Gx70mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
992090-21.1 UPC 90 21Gx90mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
992100-21.1 UPC 100 21Gx100mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
992025-24 UPC 25 24Gx25mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
992035-24 UPC 35 24Gx35mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
992050-23 UPC 50 23Gx50mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
992050-22 UPC 50 22Gx50mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
992090-22 UPC 90 22Gx90mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
992070-23 UPC 70 23Gx70mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
992070-22 UPC 70 22Gx70mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
992090-21 UPC 90 21Gx90mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
992100-21 UPC 100 21Gx100mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
992120-21 UPC 120 21Gx120mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
992150-21 UPC 150 21Gx150mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
Block BN					
BN050-22.1 Block Needle 22Gx50mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.

BN075-22.1 Block Needle 22Gx75mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
BN050-18 Block Needle 18Gx50mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
BN050-22 Block Needle 22Gx50mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
BN075-22 Block Needle 22Gx75mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
BN025-24 Block Needle 24Gx25mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
9BN050-18 Block Needle 18Gx50mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
9BN050-22 Block Needle 22Gx50mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
9BN075-22 Block Needle 22Gx75mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
9BN025-24 Block Needle 24Gx25mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
ECHOGEN USC					
USC050-22.1 USC 50 EVOLUTION 22Gx50mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
USC080-22.1 USC 80 EVOLUTION 22Gx80mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
USC090-21.1 USC 90 EVOLUTION 21Gx90mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
USC100-22.1 USC 100 EVOLUTION 21Gx100mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
USC050-22 USC 50 EVOLUTION 22Gx50mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
USCMC050-22 USCMC 50 22Gx50mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
USC070-22 USC 70 EVOLUTION 22Gx70mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.

USC080-22 USC 80 EVOLUTION 22Gx80mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
USC090-21 USC 90 EVOLUTION 21Gx90mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
USCMC090-21 USCMC 90 21Gx90mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
USC100-21 USC 100 EVOLUTION 21Gx100mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
USC120-21 USC 120 EVOLUTION 21Gx120mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
USC150-21 USC 150 EVOLUTION 21Gx150mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
9USC050-22.1 USC 50 EVOLUTION 22Gx50mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
9USC080-22.1 USC 80 EVOLUTION 22Gx80mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
9USC090-21.1 USC 90 EVOLUTION 21Gx90mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
9USC050-22 USC 50 EVOLUTION 22Gx50mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
9USC070-22 USC 70 EVOLUTION 22Gx70mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
9USC080-22 USC 80 EVOLUTION 22Gx80mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
9USC090-21 USC 90 EVOLUTION 21Gx90mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
9USC100-21 USC 100 EVOLUTION 21Gx100mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
9USC120-21 USC 120 EVOLUTION 21Gx120mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.

9USC150-21 USC 150 EVOLUTION 21Gx150mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
Echogen USB					
USB050-22.1 USB 50 EVOLUTION 22Gx50mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
USB080-22.1 USB 80 EVOLUTION 22Gx80mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
USB090-21.1 USB 90 EVOLUTION 21Gx90mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
USB100-21.1 USB 100 EVOLUTION 21Gx100mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
USB025-24 USB 25 EVOLUTION 24Gx25mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
USB035-24 USB 35 EVOLUTION 24Gx35mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
USB050-24 USB 50 EVOLUTION 24Gx50mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
USB050-22 USB 50 EVOLUTION 22Gx50mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
USB070-22 USB 70 EVOLUTION 22Gx70mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
USB080-22 USB 80 EVOLUTION 22Gx80mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
USB090-21 USB 90 EVOLUTION 21Gx90mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
USB100-21 USB 100 EVOLUTION 21Gx100mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
USB120-21 USB 120 EVOLUTION 21Gx120mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.

USB150-21 USB 150 EVOLUTION 21Gx150mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
9USB050-22.1 USB 50 EVOLUTION 22Gx50mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
9USB080-22.1 USB 80 EVOLUTION 22Gx80mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
9USB090-21.1 USB 90 EVOLUTION 21Gx90mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
9USB025-24 USB 25 EVOLUTION 24Gx25mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
9USB035-24 USB 35 EVOLUTION 24Gx35mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
9USB050-24 USB 50 EVOLUTION 24Gx35mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
9USB050-22 USB 50 EVOLUTION 22Gx50mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
9USB070-22 USB 70 EVOLUTION 22Gx70mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
9USB080-22 USB 80 EVOLUTION 22Gx80mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
9USB090-21 USB 90 EVOLUTION 21Gx90mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
9USB100-21 USB 100 EVOLUTION 21Gx100mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
9USB120-21 USB 120 EVOLUTION 21Gx120mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
9USB 150 EVOLUTION 21Gx150mm NXFitUSB150- 21	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.

COMBI-STIMULATION/ECHOGEN HYBRID C					
EH055-22.1 HYBRID C EVOLUTION 22Gx55mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
EH080-22.1 HYBRID C EVOLUTION 22Gx80 mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
EH095-21.1 HYBRID C EVOLUTION 21Gx95mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
EH035-22 HYBRID C EVOLUTION 22Gx35mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
EH055-22 HYBRID C EVOLUTION 22Gx55mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
EH050-22 HYBRID C EVOLUTION 22Gx50mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
EH080-22 HYBRID C EVOLUTION 22Gx80 mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
EH095-21 HYBRID C EVOLUTION 21Gx95mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
EH125-21 HYBRID C EVOLUTION 21Gx125mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
EH150-21 HYBRID C EVOLUTION 21Gx150mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
9EH055-22.1 HYBRID C EVOLUTION 22Gx55mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
9EH080-22.1 HYBRID C EVOLUTION 22Gx80 mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
9EH095-21.1 HYBRID C EVOLUTION 21Gx95mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
9EH035-22 HYBRID C EVOLUTION 22Gx35mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.

9EH050-22 HYBRID C EVOLUTION 22Gx50mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
9EH055-22 HYBRID C EVOLUTION 22Gx55mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
9EH080-22 HYBRID C EVOLUTION 22Gx80 mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
9EH095-21 HYBRID C EVOLUTION 21Gx95mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
9EH125-21 HYBRID C EVOLUTION 21Gx125mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
9EH150-21 HYBRID C EVOLUTION 21Gx150mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
COMBI-STIMULATION/ECHOGEN HYBRID B					
EHB055-22.1 HYBRID B EVOLUTION 22Gx55mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
EHB080-22.1 HYBRID B EVOLUTION 22Gx80mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
EHB095-21.1 HYBRID B EVOLUTION 21Gx95mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
EHB035-22 HYBRID B EVOLUTION 22Gx35mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
EHB050-22 HYBRID B EVOLUTION 22Gx50mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
EHB055-22 HYBRID B EVOLUTION 22Gx55mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
EHB055-21 HYBRID B EVOLUTION 21Gx55mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
EHB080-22 HYBRID B EVOLUTION 22Gx80mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.

EHB080-21 HYBRID B EVOLUTION 21Gx80mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
EHB095-21 HYBRID B EVOLUTION 21Gx95mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
EHB125-21 HYBRID B EVOLUTION 21Gx125mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
EHB150-21 HYBRID B EVOLUTION 21Gx150mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
9EHB055-22.1 HYBRID B EVOLUTION 22Gx55mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
9EHB080-22.1 HYBRID B EVOLUTION 22Gx80mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
9EHB095-21.1 HYBRID B EVOLUTION 21Gx95mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
9EHB035-22 HYBRID B EVOLUTION 22Gx35mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
9EHB050-22 HYBRID B EVOLUTION 22Gx50mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
9EHB055-22 HYBRID B EVOLUTION 22Gx55mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
9EHB055-21 HYBRID B EVOLUTION 21Gx55mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
9EHB080-22 HYBRID B EVOLUTION 22Gx80mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
9EHB080-21 HYBRID B EVOLUTION 21Gx80mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
9EHB095-21 HYBRID B EVOLUTION 21Gx95mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.

9EHB125-21 HYBRID B EVOLUTION 21Gx125mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
9EHB150-21 HYBRID B EVOLUTION 21Gx150mm NXFit	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
STIMULATION POLYPLEX					
04070-21 POLYPLEX N 21Gx70mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
04090-21 POLYPLEX N 21Gx90mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
19051-21 POLYPLEX C Borgeat 21Gx100mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
19032-21 POLYPLEX C Borgeat 21Gx70mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
19064-21 POLYPLEX C Borgeat 21Gx120mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
09090-21 POLYPLEX C 21Gx90mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
19030-21 POLYPLEX C 21Gx30mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
19050-21 POLYPLEX C 21Gx50mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
19065-21 POLYPLEX C 21Gx65mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
09030-18 POLYPLEX CK 18Gx30mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
09050-18 POLYPLEX CK 18Gx50mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
09070-18 POLYPLEX CK 18Gx70mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
09090-18 POLYPLEX CK 18Gx90mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
09120-18 POLYPLEX CK 18Gx120mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
09150-18 POLYPLEX CK 18Gx150mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
29150-18 POLYPLEX CK 18Gx150mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.

29030-18 POLYPLEX CK 18Gx30mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
29050-18 POLYPLEX CK 18Gx50mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
29090-18 POLYPLEX CK 18Gx90mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
06030-21 POLYPLEX B 21Gx30mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
06050-21 POLYPLEX B 21Gx50mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
06090-21 POLYPLEX B 21Gx90mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
08050-18 POLYPLEX T 18Gx50mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
08090-18 POLYPLEX T 18Gx90mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
08120-18 POLYPLEX T 18Gx120mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
08150-18 POLYPLEX T 18Gx150mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
26951-18 ECHO POLYPLEX 18Gx50mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.
26991-18 ECHO POLYPLEX 18Gx90mm	Z/18/04251D	16.06.2023	ecm 0481	31.12.2028	n.a.