



Notified Body Confirmation Letter Reference: C694714

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, DNV Product Assurance AS, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number NB 2460 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:

**Atos Medical AB
Kraftgatan 8
SE-24235 Hörby
Sweden**

SRN Number: SE-MF-000000725, SE-IM-000005223 , SE-PR-000040682

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB 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 NB 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issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

Place and date:
Høvik, 13.02.2025

For the issuing office:
DNV Product Assurance AS – Notified Body 2460
Veritasveien 1, 1363 Høvik, Norway



Menaka Singh
Management Representative

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)

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Devicename:Provox Vega 17Fr 4mm - REF: 4270 - Basic UDI: 7331791-VPS-0-0E0-0002-N2	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega 17Fr 6mm - REF: 4271 - Basic UDI: 7331791-VPS-0-0E0-0002-N2	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega 17Fr 8mm - REF: 4272 - Basic UDI: 7331791-VPS-0-0E0-0002-N2	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega 17Fr 10mm - REF: 4273 - Basic UDI: 7331791-VPS-0-0E0-0002-N2	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega 17Fr 12.5mm - REF: 4274 - Basic UDI: 7331791-VPS-0-0E0-0002-N2	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega 17Fr 15mm - REF: 4275 - Basic UDI: 7331791-VPS-0-0E0-0002-N2	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega 20Fr 4mm - REF: 4276 - Basic UDI: 7331791-VPS-0-0E0-0002-N2	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega 20Fr 6mm - REF: 4277 - Basic UDI: 7331791-VPS-0-0E0-0002-N2	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega 20Fr 8mm - REF: 4278 - Basic UDI: 7331791-VPS-0-0E0-0002-N2	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega 20Fr 10mm - REF: 4279 - Basic UDI: 7331791-VPS-0-0E0-0002-N2	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega 20Fr 12.5mm - REF: 4280 - Basic UDI: 7331791-VPS-0-0E0-0002-N2	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega 20Fr 15mm - REF: 4281 - Basic UDI: 7331791-VPS-0-0E0-0002-N2	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega 22.5Fr 4mm -	IIb	N/A	41310296-04

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
REF: 4282 - Basic UDI: 7331791-VPS-0-0E0-0002-N2			Intertek (0413)
Devicename:Provox Vega 22.5Fr 6mm - REF: 4283 - Basic UDI: 7331791-VPS-0-0E0-0002-N2	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega 22.5Fr 8mm - REF: 4284 - Basic UDI: 7331791-VPS-0-0E0-0002-N2	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega 22.5Fr 10mm - REF: 4285 - Basic UDI: 7331791-VPS-0-0E0-0002-N2	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega 22.5Fr 12.5mm - REF: 4286 - Basic UDI: 7331791-VPS-0-0E0-0002-N2	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega 22.5Fr 15mm - REF: 4287 - Basic UDI: 7331791-VPS-0-0E0-0002-N2	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega XtraSeal 17Fr 4mm - REF: 4288 - Basic UDI: 7331791-VPS-0-0E0-0004-N8	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega XtraSeal 17Fr 6mm - REF: 4289 - Basic UDI: 7331791-VPS-0-0E0-0004-N8	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega XtraSeal 17Fr 8mm - REF: 4290 - Basic UDI: 7331791-VPS-0-0E0-0004-N8	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega XtraSeal 17Fr 10mm - REF: 4291 - Basic UDI: 7331791-VPS-0-0E0-0004-N8	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega XtraSeal 17Fr 12.5mm - REF: 4292 - Basic UDI: 7331791-VPS-0-0E0-0004-N8	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega XtraSeal 17Fr 15mm - REF: 4293 - Basic UDI: 7331791-VPS-0-0E0-0004-N8	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega XtraSeal 20Fr 4mm - REF: 4294 - Basic UDI: 7331791-VPS-0-0E0-0004-N8	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega XtraSeal 20Fr 6mm - REF: 4295 - Basic UDI: 7331791-VPS-0-0E0-0004-N8	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega XtraSeal 20Fr 8mm - REF: 4296 - Basic UDI: 7331791-VPS-0-0E0-0004-N8	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega XtraSeal 20Fr 10mm - REF: 4297 - Basic UDI: 7331791-VPS-0-0E0-0004-N8	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega XtraSeal 20Fr 12.5mm - REF: 4298 - Basic UDI: 7331791-VPS-0-0E0-0004-N8	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega XtraSeal 20Fr 15mm - REF: 4299 - Basic UDI: 7331791-VPS-0-0E0-0004-N8	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega XtraSeal 22.5Fr 4mm - REF: 4300 - Basic UDI: 7331791-VPS-0-0E0-0004-N8	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega XtraSeal 22.5Fr 6mm - REF: 4301 - Basic UDI: 7331791-VPS-0-0E0-0004-N8	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega XtraSeal 22.5Fr 8mm - REF: 4302 - Basic UDI: 7331791-VPS-0-0E0-0004-N8	IIb	N/A	41310296-04 Intertek (0413)

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Devicename:Provox Vega XtraSeal 22.5Fr 10mm - REF: 4303 - Basic UDI: 7331791-VPS-0-0E0-0004-N8	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega XtraSeal 22.5Fr 12.5mm - REF: 4304 - Basic UDI: 7331791-VPS-0-0E0-0004-N8	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega XtraSeal 22.5Fr 15mm - REF: 4305 - Basic UDI: 7331791-VPS-0-0E0-0004-N8	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox NID 17, 6 mm - REF: 7101 - Basic UDI: 7331791-VPS-0-000-0000-9Y	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox NID 17, 8 mm - REF: 7102 - Basic UDI: 7331791-VPS-0-000-0000-9Y	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox NID 17, 10 mm - REF: 7103 - Basic UDI: 7331791-VPS-0-000-0000-9Y	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox NID 17, 12 mm - REF: 7104 - Basic UDI: 7331791-VPS-0-000-0000-9Y	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox NID 17, 14 mm - REF: 7105 - Basic UDI: 7331791-VPS-0-000-0000-9Y	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox NID 17, 18 mm - REF: 7106 - Basic UDI: 7331791-VPS-0-000-0000-9Y	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox NID 20, 6 mm - REF: 7111 - Basic UDI: 7331791-VPS-0-000-0000-9Y	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox NID 20, 8 mm - REF: 7112 - Basic UDI: 7331791-VPS-0-000-0000-9Y	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox NID 20, 10 mm - REF: 7113 - Basic UDI: 7331791-VPS-0-000-0000-9Y	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox NID 20, 12 mm - REF: 7114 - Basic UDI: 7331791-VPS-0-000-0000-9Y	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox NID 20, 14 mm - REF: 7115 - Basic UDI: 7331791-VPS-0-000-0000-9Y	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox NID 20, 18 mm - REF: 7116 - Basic UDI: 7331791-VPS-0-000-0000-9Y	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Dilator 17 - REF: 7122 - Basic UDI: 7331791-VPS-A-00R-0010-B9	IIa	N/A	41310296-04 Intertek (0413)
Devicename:Provox Dilator 20 - REF: 7123 - Basic UDI: 7331791-VPS-A-00R-0010-B9	IIa	N/A	41310296-04 Intertek (0413)
Devicename:Provox ActiValve Lubricant - REF: 7149 - Basic UDI: 7331791-GEN-A-000-0004-EJ	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox ActiValve Light 4.5 mm - REF: 7150 - Basic UDI: 7331791-VPS-0-000-0001-A3	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox ActiValve Light 6 mm - REF: 7151 - Basic UDI: 7331791-VPS-0-000-0001-A3	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox ActiValve Light 8 mm - REF: 7152 - Basic UDI: 7331791-	IIb	N/A	41310296-04 Intertek (0413)

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VPS-0-000-0001-A3 Devicename:Provox ActiValve Light 10 mm - REF: 7153 - Basic UDI: 7331791-VPS-0-000-0001-A3	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox ActiValve Light 12.5 mm - REF: 7154 - Basic UDI: 7331791-VPS-0-000-0001-A3	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox ActiValve Strong 4.5 mm - REF: 7160 - Basic UDI: 7331791-VPS-0-000-0001-A3	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox ActiValve Strong 6 mm - REF: 7161 - Basic UDI: 7331791-VPS-0-000-0001-A3	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox ActiValve Strong 8 mm - REF: 7162 - Basic UDI: 7331791-VPS-0-000-0001-A3	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox ActiValve Strong 10 mm - REF: 7163 - Basic UDI: 7331791-VPS-0-000-0001-A3	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox ActiValve Strong 12.5 mm - REF: 7164 - Basic UDI: 7331791-VPS-0-000-0001-A3	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox ActiValve XtraStrong 4.5 mm - REF: 7165 - Basic UDI: 7331791-VPS-0-000-0001-A3	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox ActiValve XtraStrong 6 mm - REF: 7166 - Basic UDI: 7331791-VPS-0-000-0001-A3	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox ActiValve XtraStrong 8 mm - REF: 7167 - Basic UDI: 7331791-VPS-0-000-0001-A3	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox ActiValve XtraStrong 10 mm - REF: 7168 - Basic UDI: 7331791-VPS-0-000-0001-A3	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox ActiValve XtraStrong 12.5 mm - REF: 7169 - Basic UDI: 7331791-VPS-0-000-0001-A3	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Plug - REF: 7205 - Basic UDI: 7331791-VPS-A-000-0004-RU	IIa	N/A	41310296-04 Intertek (0413)
Devicename:Provox Dilator - REF: 7211 - Basic UDI: 7331791-VPS-A-00R-0007-BR	IIa	N/A	41310296-04 Intertek (0413)
Devicename:Provox GuideWire - REF: 7215 - Basic UDI: 7331791-VPS-A-0E0-0006-5Z	IIa	N/A	41310296-04 Intertek (0413)
Devicename:Provox2 Voice Prosthesis 4.5mm - REF: 7216 - Basic UDI: 7331791-VPS-0-0E0-0005-NB	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox2 Voice Prosthesis 6mm - REF: 7217 - Basic UDI: 7331791-VPS-0-0E0-0005-NB	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox2 Voice Prosthesis 8mm - REF: 7218 - Basic UDI: 7331791-VPS-0-0E0-0005-NB	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox2 Voice Prosthesis 10mm - REF: 7219 - Basic UDI: 7331791-VPS-0-0E0-0005-NB	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox2 Voice Prosthesis 12.5mm - REF: 7221 - Basic UDI: 7331791-VPS-0-0E0-0005-NB	IIb	N/A	41310296-04 Intertek (0413)

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Devicename:Provox2 Voice Prosthesis 15mm - REF: 7224 - Basic UDI: 7331791-VPS-0-0E0-0005-NB	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox XtraFlange 22.5 - REF: 7275 - Basic UDI: 7331791-VPS-A-0E0-0008-67	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox XtraFlange 20 - REF: 7276 - Basic UDI: 7331791-VPS-A-0E0-0008-67	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox XtraFlange 17 - REF: 7277 - Basic UDI: 7331791-VPS-A-0E0-0008-67	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Life LaryTube 8/27 Standard - REF: 7409 - Basic UDI: 7331791-LTU-0-000-0004-3L	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Life LaryTube 8/36 Standard - REF: 7410 - Basic UDI: 7331791-LTU-0-000-0004-3L	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Life LaryTube 8/55 Standard - REF: 7411 - Basic UDI: 7331791-LTU-0-000-0004-3L	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Life LaryTube 9/27 Standard - REF: 7412 - Basic UDI: 7331791-LTU-0-000-0004-3L	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Life LaryTube 9/36 Standard - REF: 7413 - Basic UDI: 7331791-LTU-0-000-0004-3L	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Life LaryTube 9/55 Standard - REF: 7414 - Basic UDI: 7331791-LTU-0-000-0004-3L	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Life LaryTube 10/27 Standard - REF: 7415 - Basic UDI: 7331791-LTU-0-000-0004-3L	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Life LaryTube 10/36 Standard - REF: 7416 - Basic UDI: 7331791-LTU-0-000-0004-3L	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Life LaryTube 10/55 Standard - REF: 7417 - Basic UDI: 7331791-LTU-0-000-0004-3L	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Life LaryTube 12/27 Standard - REF: 7418 - Basic UDI: 7331791-LTU-0-000-0004-3L	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Life LaryTube 12/36 Standard - REF: 7419 - Basic UDI: 7331791-LTU-0-000-0004-3L	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Life LaryTube 12/55 Standard - REF: 7420 - Basic UDI: 7331791-LTU-0-000-0004-3L	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Life LaryTube 8/36 Standard with Ring - REF: 7421 - Basic UDI: 7331791-LTU-0-000-0004-3L	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Life LaryTube 8/55 Standard with Ring - REF: 7422 - Basic UDI: 7331791-LTU-0-000-0004-3L	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Life LaryTube 9/36 Standard with Ring - REF: 7423 - Basic UDI: 7331791-LTU-0-000-0004-3L	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Life LaryTube 9/55 Standard with Ring - REF: 7424 - Basic UDI: 7331791-LTU-0-000-0004-3L	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Life LaryTube10/36 Standard with Ring - REF: 7425 - Basic	IIb	N/A	41310296-04 Intertek (0413)

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UDI: 7331791-LTU-0-000-0004-3L			
Devicename:Provox Life LaryTube 10/55 Standard with Ring - REF: 7426 - Basic UDI: 7331791-LTU-0-000-0004-3L	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Life LaryTube 12/36 Standard with Ring - REF: 7427 - Basic UDI: 7331791-LTU-0-000-0004-3L	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Life LaryTube 12/55 Standard with Ring - REF: 7428 - Basic UDI: 7331791-LTU-0-000-0004-3L	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Life LaryTube 8/36, Fenestrated - REF: 7429 - Basic UDI: 7331791-LTU-0-000-0004-3L	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Life LaryTube 8/55, Fenestrated - REF: 7430 - Basic UDI: 7331791-LTU-0-000-0004-3L	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Life LaryTube 9/36, Fenestrated - REF: 7431 - Basic UDI: 7331791-LTU-0-000-0004-3L	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Life LaryTube 9/55, Fenestrated - REF: 7432 - Basic UDI: 7331791-LTU-0-000-0004-3L	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Life LaryTube 10/36, Fenestrated - REF: 7433 - Basic UDI: 7331791-LTU-0-000-0004-3L	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Life LaryTube 10/55, Fenestrated - REF: 7434 - Basic UDI: 7331791-LTU-0-000-0004-3L	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Life LaryTube 12/36, Fenestrated - REF: 7435 - Basic UDI: 7331791-LTU-0-000-0004-3L	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Life LaryTube 12/55, Fenestrated - REF: 7436 - Basic UDI: 7331791-LTU-0-000-0004-3L	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox LaryTube 8/27 - REF: 7601 - Basic UDI: 7331791-LTU-0-000-0002-3E	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox LaryTube 8/36 - REF: 7602 - Basic UDI: 7331791-LTU-0-000-0002-3E	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox LaryTube 8/55 - REF: 7603 - Basic UDI: 7331791-LTU-0-000-0002-3E	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox LaryTube 9/27 - REF: 7605 - Basic UDI: 7331791-LTU-0-000-0002-3E	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox LaryTube 9/36 - REF: 7606 - Basic UDI: 7331791-LTU-0-000-0002-3E	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox LaryTube 9/55 - REF: 7607 - Basic UDI: 7331791-LTU-0-000-0002-3E	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox LaryTube 10/27 - REF: 7609 - Basic UDI: 7331791-LTU-0-000-0002-3E	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox LaryTube 10/36 - REF: 7610 - Basic UDI: 7331791-LTU-0-000-0002-3E	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox LaryTube 10/55 -	IIb	N/A	41310296-04

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
REF: 7611 - Basic UDI: 7331791-LTU-0-000-0002-3E			Intertek (0413)
Devicename:Provox LaryTube 12/27 - REF: 7613 - Basic UDI: 7331791-LTU-0-000-0002-3E	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox LaryTube 12/36 - REF: 7614 - Basic UDI: 7331791-LTU-0-000-0002-3E	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox LaryTube 12/55 - REF: 7615 - Basic UDI: 7331791-LTU-0-000-0002-3E	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox LaryTube 8/36 with Ring - REF: 7624 - Basic UDI: 7331791-LTU-0-000-0002-3E	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox LaryTube 8/55 with Ring - REF: 7625 - Basic UDI: 7331791-LTU-0-000-0002-3E	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox LaryTube 9/36 with Ring - REF: 7626 - Basic UDI: 7331791-LTU-0-000-0002-3E	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox LaryTube 9/55 with Ring - REF: 7627 - Basic UDI: 7331791-LTU-0-000-0002-3E	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox LaryTube 10/36 with Ring - REF: 7628 - Basic UDI: 7331791-LTU-0-000-0002-3E	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox LaryTube 10/55 with Ring - REF: 7629 - Basic UDI: 7331791-LTU-0-000-0002-3E	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox LaryTube 12/36 with Ring - REF: 7630 - Basic UDI: 7331791-LTU-0-000-0002-3E	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox LaryTube 12/55 with Ring - REF: 7631 - Basic UDI: 7331791-LTU-0-000-0002-3E	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox LaryTube 8/36, Fenestrated - REF: 7637 - Basic UDI: 7331791-LTU-0-000-0002-3E	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox LaryTube 8/55, Fenestrated - REF: 7638 - Basic UDI: 7331791-LTU-0-000-0002-3E	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox LaryTube 9/36, Fenestrated - REF: 7640 - Basic UDI: 7331791-LTU-0-000-0002-3E	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox LaryTube 9/55, Fenestrated - REF: 7641 - Basic UDI: 7331791-LTU-0-000-0002-3E	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox LaryTube 10/36, Fenestrated - REF: 7643 - Basic UDI: 7331791-LTU-0-000-0002-3E	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox LaryTube 10/55, Fenestrated - REF: 7644 - Basic UDI: 7331791-LTU-0-000-0002-3E	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox LaryTube 12/36, Fenestrated - REF: 7646 - Basic UDI: 7331791-LTU-0-000-0002-3E	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox LaryTube 12/55, Fenestrated - REF: 7647 - Basic UDI: 7331791-LTU-0-000-0002-3E	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox LaryButton 12/8 - REF: 7671 - Basic UDI: 7331791-LTU-0-000-0000-38	IIb	N/A	41310296-04 Intertek (0413)

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Devicename:Provox LaryButton 14/8 - REF: 7672 - Basic UDI: 7331791-LTU-0-000-0000-38	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox LaryButton 16/8 - REF: 7673 - Basic UDI: 7331791-LTU-0-000-0000-38	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox LaryButton 18/8 - REF: 7674 - Basic UDI: 7331791-LTU-0-000-0000-38	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox LaryButton 12/18 - REF: 7685 - Basic UDI: 7331791-LTU-0-000-0000-38	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox LaryButton 14/18 - REF: 7686 - Basic UDI: 7331791-LTU-0-000-0000-38	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox LaryButton 16/18 - REF: 7687 - Basic UDI: 7331791-LTU-0-000-0000-38	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox LaryButton 18/18 - REF: 7688 - Basic UDI: 7331791-LTU-0-000-0000-38	IIb	N/A	41310296-04 Intertek (0413)
Devicename:TrachPhone (50 pcs) - REF: 7704 - Basic UDI: 7331791-HME-0-000-0006-XT	IIa	N/A	41310296-04 Intertek (0413)
Devicename:MEDIFLUX HCH F6 (Medival) - REF: 7705 - Basic UDI: 7331791-HME-0-000-0006-XT	IIa	N/A	41310296-04 Intertek (0413)
Devicename:TrachPhone (30 pcs) - REF: 7707 - Basic UDI: 7331791-HME-0-000-0006-XT	IIa	N/A	41310296-04 Intertek (0413)
Devicename:TrachPhone (5 pcs) - REF: 7723 - Basic UDI: 7331791-HME-0-000-0006-XT	IIa	N/A	41310296-04 Intertek (0413)
Devicename:HME DigiTop O2 - REF: 7756 - Basic UDI: 7331791-HME-A-000-0007-FH	IIa	N/A	41310296-04 Intertek (0413)
Devicename:Freevent O2 Adaptor 10pcs - REF: 7769 - Basic UDI: 7331791-HME-A-000-0001-EX	IIa	N/A	41310296-04 Intertek (0413)
Devicename:Freevent O2 Adaptor Mini 10 pcs - REF: 8007 - Basic UDI: 7331791-HME-A-000-0001-EX	IIa	N/A	41310296-04 Intertek (0413)
Devicename:Freevent Dressing Softfoam L - REF: 8034 - Basic UDI: 7331791-COM-0-0G0-0002-J7	Is	N/A	41310296-04 Intertek (0413)
Devicename:Freevent Dressing Softfoam S - REF: 8035 - Basic UDI: 7331791-COM-0-0G0-0002-J7	Is	N/A	41310296-04 Intertek (0413)
Devicename:Freevent Dressing Softfoam Slim L - REF: 8036 - Basic UDI: 7331791-COM-0-0G0-0002-J7	Is	N/A	41310296-04 Intertek (0413)
Devicename:Provox Life LaryButton 12/8 - REF: 8040 - Basic UDI: 7331791-LTU-0-000-0005-3P	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Life LaryButton 12/18 - REF: 8041 - Basic UDI: 7331791-LTU-0-000-0005-3P	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Life LaryButton 14/8 - REF: 8042 - Basic UDI: 7331791-LTU-0-000-0005-3P	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Life LaryButton 14/18 - REF: 8043 - Basic UDI:	IIb	N/A	41310296-04 Intertek (0413)

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
7331791-LTU-0-000-0005-3P			
Devicename:Provox Life LaryButton 16/8 - REF: 8044 - Basic UDI: 7331791-LTU-0-000-0005-3P	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Life LaryButton 16/8 - REF: 8045 - Basic UDI: 7331791-LTU-0-000-0005-3P	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Life LaryButton 18/8 - REF: 8046 - Basic UDI: 7331791-LTU-0-000-0005-3P	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Life LaryButton 18/18 - REF: 8047 - Basic UDI: 7331791-LTU-0-000-0005-3P	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Life LaryTube 8/36 Fenestrated with Ring - REF: 8048 - Basic UDI: 7331791-LTU-0-000-0004-3L	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Life LaryTube 8/55 Fenestrated with Ring - REF: 8049 - Basic UDI: 7331791-LTU-0-000-0004-3L	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Life LaryTube 9/36 Fenestrated with Ring - REF: 8050 - Basic UDI: 7331791-LTU-0-000-0004-3L	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Life LaryTube 9/55 Fenestrated with Ring - REF: 8051 - Basic UDI: 7331791-LTU-0-000-0004-3L	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Life LaryTube 10/36 Fenestrated with Ring - REF: 8052 - Basic UDI: 7331791-LTU-0-000-0004-3L	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Life LaryTube 10/55 Fenestrated with Ring - REF: 8053 - Basic UDI: 7331791-LTU-0-000-0004-3L	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Life LaryTube 12/36 Fenestrated with Ring - REF: 8054 - Basic UDI: 7331791-LTU-0-000-0004-3L	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Life LaryTube 12/55 Fenestrated with Ring - REF: 8055 - Basic UDI: 7331791-LTU-0-000-0004-3L	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega Plug 17 - REF: 8119 - Basic UDI: 7331791-VPS-A-000-0004-RU	IIa	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega Plug 20 - REF: 8129 - Basic UDI: 7331791-VPS-A-000-0004-RU	IIa	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega Plug 22.5 - REF: 8139 - Basic UDI: 7331791-VPS-A-000-0004-RU	IIa	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega Puncture Set 17Fr 8mm - REF: 8140 - Basic UDI: 7331791-VPS-0-0EI-0003-2Y	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega Puncture Set 17Fr 10mm - REF: 8141 - Basic UDI: 7331791-VPS-0-0EI-0003-2Y	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega Puncture Set 17Fr 12.5mm - REF: 8142 - Basic UDI:	IIb	N/A	41310296-04 Intertek (0413)

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
7331791-VPS-0-0EI-0003-2Y Devicename:Provox Vega Puncture Set 17Fr 15mm - REF: 8143 - Basic UDI: 7331791-VPS-0-0EI-0003-2Y	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega Puncture Set 20Fr 8mm - REF: 8144 - Basic UDI: 7331791-VPS-0-0EI-0003-2Y	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega Puncture Set 20Fr 10mm - REF: 8145 - Basic UDI: 7331791-VPS-0-0EI-0003-2Y	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega Puncture Set 20Fr 12.5mm - REF: 8146 - Basic UDI: 7331791-VPS-0-0EI-0003-2Y	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega Puncture Set 22.5Fr 8mm - REF: 8147 - Basic UDI: 7331791-VPS-0-0EI-0003-2Y	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega Puncture Set 22.5Fr 10mm - REF: 8148 - Basic UDI: 7331791-VPS-0-0EI-0003-2Y	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega Puncture Set 22.5Fr 12.5mm - REF: 8149 - Basic UDI: 7331791-VPS-0-0EI-0003-2Y	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega 17Fr 4mm - REF: 8270 - Basic UDI: 7331791-VPS-0-0E0-0002-N2	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega 17Fr 6mm - REF: 8271 - Basic UDI: 7331791-VPS-0-0E0-0002-N2	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega 17Fr 8mm - REF: 8272 - Basic UDI: 7331791-VPS-0-0E0-0002-N2	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega 17Fr 10mm - REF: 8273 - Basic UDI: 7331791-VPS-0-0E0-0002-N2	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega 17Fr 12.5mm - REF: 8274 - Basic UDI: 7331791-VPS-0-0E0-0002-N2	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega 17Fr 15mm - REF: 8275 - Basic UDI: 7331791-VPS-0-0E0-0002-N2	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega 20Fr 4mm - REF: 8276 - Basic UDI: 7331791-VPS-0-0E0-0002-N2	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega 20Fr 6mm - REF: 8277 - Basic UDI: 7331791-VPS-0-0E0-0002-N2	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega 20Fr 8mm - REF: 8278 - Basic UDI: 7331791-VPS-0-0E0-0002-N2	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega 20Fr 10mm - REF: 8279 - Basic UDI: 7331791-VPS-0-0E0-0002-N2	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega 20Fr 12.5mm - REF: 8280 - Basic UDI: 7331791-VPS-0-0E0-0002-N2	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega 20Fr 15mm - REF: 8281 - Basic UDI: 7331791-VPS-0-0E0-0002-N2	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega 22.5Fr 4mm - REF: 8282 - Basic UDI: 7331791-VPS-0-0E0-0002-N2	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega 22.5Fr 6mm -	IIb	N/A	41310296-04

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
REF: 8283 - Basic UDI: 7331791-VPS-0-0E0-0002-N2			Intertek (0413)
Devicename:Provox Vega 22.5Fr 8mm - REF: 8284 - Basic UDI: 7331791-VPS-0-0E0-0002-N2	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega 22.5Fr 10mm - REF: 8285 - Basic UDI: 7331791-VPS-0-0E0-0002-N2	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega 22.5Fr 12.5mm - REF: 8286 - Basic UDI: 7331791-VPS-0-0E0-0002-N2	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega 22.5Fr 15mm - REF: 8287 - Basic UDI: 7331791-VPS-0-0E0-0002-N2	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega XtraSeal 17Fr 4mm - REF: 8288 - Basic UDI: 7331791-VPS-0-0E0-0004-N8	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega XtraSeal 17Fr 6mm - REF: 8289 - Basic UDI:7331791-VPS-0-0E0-0004-N8	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega XtraSeal 17Fr 8mm - REF: 8290 - Basic UDI: 7331791-VPS-0-0E0-0004-N8	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega XtraSeal 17Fr 10mm - REF: 8291 - Basic UDI: 7331791-VPS-0-0E0-0004-N8	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega XtraSeal 17Fr 12.5mm - REF: 8292 - Basic UDI: 7331791-VPS-0-0E0-0004-N8	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega XtraSeal 17Fr 15mm - REF: 8293 - Basic UDI: 7331791-VPS-0-0E0-0004-N8	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega XtraSeal 20Fr 4mm - REF: 8294 - Basic UDI: 7331791-VPS-0-0E0-0004-N8	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega XtraSeal 20Fr 6mm - REF: 8295 - Basic UDI: 7331791-VPS-0-0E0-0004-N8	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega XtraSeal 20Fr 8mm - REF: 8296 - Basic UDI: 7331791-VPS-0-0E0-0004-N8	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega XtraSeal 20Fr 10mm - REF: 8297 - Basic UDI: 7331791-VPS-0-0E0-0004-N8	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega XtraSeal 20Fr 12.5mm - REF: 8298 - Basic UDI: 7331791-VPS-0-0E0-0004-N8	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega XtraSeal 20Fr 15mm - REF: 8299 - Basic UDI: 7331791-VPS-0-0E0-0004-N8	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega XtraSeal 22.5Fr 4mm - REF: 8300 - Basic UDI: 7331791-VPS-0-0E0-0004-N8	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega XtraSeal 22.5Fr 6mm - REF: 8301 - Basic UDI: 7331791-VPS-0-0E0-0004-N8	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega XtraSeal 22.5Fr 8mm - REF: 8302 - Basic UDI: 7331791-VPS-0-0E0-0004-N8	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega XtraSeal 22.5Fr 10mm - REF: 8303 - Basic UDI: 7331791-VPS-0-0E0-0004-N8	IIb	N/A	41310296-04 Intertek (0413)

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Devicename:Provox Vega XtraSeal 22.5Fr 12.5mm - REF: 8304 - Basic UDI: 7331791-VPS-0-0E0-0004-N8	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega XtraSeal 22.5Fr 15mm - REF: 8305 - Basic UDI: 7331791-VPS-0-0E0-0004-N8	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox LaryTube 8/27 - REF: 7601FR - Basic UDI: 7331791-LTU-0-000-0002-3E	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox LaryTube 8/36 - REF: 7602FR - Basic UDI: 7331791-LTU-0-000-0002-3E	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox LaryTube 8/55 - REF: 7603FR - Basic UDI: 7331791-LTU-0-000-0002-3E	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox LaryTube 9/27 - REF: 7605FR - Basic UDI: 7331791-LTU-0-000-0002-3E	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox LaryTube 9/36 - REF: 7606FR - Basic UDI: 7331791-LTU-0-000-0002-3E	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox LaryTube 9/55 - REF: 7607FR - Basic UDI: 7331791-LTU-0-000-0002-3E	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox LaryTube 10/27 - REF: 7609FR - Basic UDI: 7331791-LTU-0-000-0002-3E	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox LaryTube 10/36 - REF: 7610FR - Basic UDI: 7331791-LTU-0-000-0002-3E	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox LaryTube 10/55 - REF: 7611FR - Basic UDI: 7331791-LTU-0-000-0002-3E	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox LaryTube 12/27 - REF: 7613FR - Basic UDI: 7331791-LTU-0-000-0002-3E	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox LaryTube 12/36 - REF: 7614FR - Basic UDI: 7331791-LTU-0-000-0002-3E	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox LaryTube 12/55 - REF: 7615FR - Basic UDI: 7331791-LTU-0-000-0002-3E	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox LaryTube 8/36 with Ring - REF: 7624FR - Basic UDI: 7331791-LTU-0-000-0002-3E	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox LaryTube 8/55 with Ring - REF: 7625FR - Basic UDI: 7331791-LTU-0-000-0002-3E	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox LaryTube 9/36 with Ring - REF: 7626FR - Basic UDI: 7331791-LTU-0-000-0002-3E	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox LaryTube 9/55 with Ring - REF: 7627FR - Basic UDI: 7331791-LTU-0-000-0002-3E	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox LaryTube 10/36 with Ring - REF: 7628FR - Basic UDI: 7331791-LTU-0-000-0002-3E	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox LaryTube 10/55 with Ring - REF: 7629FR - Basic UDI: 7331791-LTU-0-000-0002-3E	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox LaryTube 12/36 with Ring - REF: 7630FR - Basic UDI:	IIb	N/A	41310296-04 Intertek (0413)

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
7331791-LTU-0-000-0002-3E			
Devicename:Provox LaryTube 12/55 with Ring - REF: 7631FR - Basic UDI: 7331791-LTU-0-000-0002-3E	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox LaryTube 8/36, Fenestrated - REF: 7637FR - Basic UDI: 7331791-LTU-0-000-0002-3E	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox LaryTube 8/55, Fenestrated - REF: 7638FR - Basic UDI: 7331791-LTU-0-000-0002-3E	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox LaryTube 9/36, Fenestrated - REF: 7640FR - Basic UDI: 7331791-LTU-0-000-0002-3E	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox LaryTube 9/55, Fenestrated - REF: 7641FR - Basic UDI: 7331791-LTU-0-000-0002-3E	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox LaryTube 10/36, Fenestrated - REF: 7643FR - Basic UDI: 7331791-LTU-0-000-0002-3E	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox LaryTube 10/55, Fenestrated - REF: 7644FR - Basic UDI: 7331791-LTU-0-000-0002-3E	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox LaryTube 12/36, Fenestrated - REF: 7646FR - Basic UDI: 7331791-LTU-0-000-0002-3E	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox LaryTube 12/55, Fenestrated - REF: 7647FR - Basic UDI: 7331791-LTU-0-000-0002-3E	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega Puncture Set 17Fr 8mm - REF: 8140-18 - Basic UDI: 7331791-VPS-0-0EI-0003-2Y	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega Puncture Set 17Fr 8mm - REF: 8140US - Basic UDI: 7331791-VPS-0-0EI-0003-2Y	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega Puncture Set 17Fr 10mm - REF: 8141-18 - Basic UDI: 7331791-VPS-0-0EI-0003-2Y	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega Puncture Set 17Fr 10mm - REF: 8141US - Basic UDI: 7331791-VPS-0-0EI-0003-2Y	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega Puncture Set 17Fr 12.5mm - REF: 8142-18 - Basic UDI: 7331791-VPS-0-0EI-0003-2Y	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega Puncture Set 17Fr 12.5mm - REF: 8142US - Basic UDI: 7331791-VPS-0-0EI-0003-2Y	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega Puncture Set 17Fr 15mm - REF: 8143-18 - Basic UDI: 7331791-VPS-0-0EI-0003-2Y	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega Puncture Set 17Fr 15mm - REF: 8143US - Basic UDI: 7331791-VPS-0-0EI-0003-2Y	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega Puncture Set 20Fr 8mm - REF: 8144-18 - Basic UDI: 7331791-VPS-0-0EI-0003-2Y	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega Puncture Set 20Fr 8mm - REF: 8144US - Basic UDI: 7331791-VPS-0-0EI-0003-2Y	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega Puncture Set 20Fr 10mm - REF: 8145-18 - Basic UDI: 7331791-VPS-0-0EI-0003-2Y	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega Puncture Set	IIb	N/A	41310296-04

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
20Fr 10mm - REF: 8145US - Basic UDI: 7331791-VPS-0-0EI-0003-2Y			Intertek (0413)
Devicename:Provox Vega Puncture Set 20Fr 12.5mm - REF: 8146-18 - Basic UDI: 7331791-VPS-0-0EI-0003-2Y	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega Puncture Set 20Fr 12.5mm - REF: 8146US - Basic UDI: 7331791-VPS-0-0EI-0003-2Y	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega Puncture Set 22.5Fr 8mm - REF: 8147-18 - Basic UDI: 7331791-VPS-0-0EI-0003-2Y	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega Puncture Set 22.5Fr 8mm - REF: 8147US - Basic UDI: 7331791-VPS-0-0EI-0003-2Y	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega Puncture Set 22.5Fr 10mm - REF: 8148-18 - Basic UDI: 7331791-VPS-0-0EI-0003-2Y	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega Puncture Set 22.5Fr 10mm - REF: 8148US - Basic UDI: 7331791-VPS-0-0EI-0003-2Y	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega Puncture Set 22.5Fr 12.5mm - REF: 8149-18 - Basic UDI: 7331791-VPS-0-0EI-0003-2Y	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega Puncture Set 22.5Fr 12.5mm - REF: 8149US - Basic UDI: 7331791-VPS-0-0EI-0003-2Y	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega 17Fr 4mm - REF: 8270-18 - Basic UDI: 7331791-VPS-0-0E0-0002-N2	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega 17Fr 6mm - REF: 8271-18 - Basic UDI: 7331791-VPS-0-0E0-0002-N2	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega 17Fr 8mm - REF: 8272-18 - Basic UDI: 7331791-VPS-0-0E0-0002-N2	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega 17Fr 10mm - REF: 8273-18 - Basic UDI: 7331791-VPS-0-0E0-0002-N2	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega 17Fr 12.5mm - REF: 8274-18 - Basic UDI: 7331791-VPS-0-0E0-0002-N2	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega 17Fr 15mm - REF: 8275-18 - Basic UDI: 7331791-VPS-0-0E0-0002-N2	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega 20Fr 4mm - REF: 8276-18 - Basic UDI: 7331791-VPS-0-0E0-0002-N2	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega 20Fr 6mm - REF: 8277-18 - Basic UDI: 7331791-VPS-0-0E0-0002-N2	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega 20Fr 8mm - REF: 8278-18 - Basic UDI: 7331791-VPS-0-0E0-0002-N2	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega 20Fr 10mm - REF: 8279-18 - Basic UDI: 7331791-VPS-0-0E0-0002-N2	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega 20Fr 12.5mm - REF: 8280-18 - Basic UDI: 7331791-VPS-0-0E0-0002-N2	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega 20Fr 15mm - REF: 8281-18 - Basic UDI: 7331791-VPS-0-0E0-0002-N2	IIb	N/A	41310296-04 Intertek (0413)

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Devicename:Provox Vega 22.5Fr 4mm - REF: 8282-18 - Basic UDI: 7331791-VPS-0-0E0-0002-N2	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega 22.5Fr 6mm - REF: 8283-18 - Basic UDI: 7331791-VPS-0-0E0-0002-N2	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega 22.5Fr 8mm - REF: 8284-18 - Basic UDI: 7331791-VPS-0-0E0-0002-N2	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega 22.5Fr 10mm - REF: 8285-18 - Basic UDI: 7331791-VPS-0-0E0-0002-N2	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega 22.5Fr 12.5mm - REF: 8286-18 - Basic UDI: 7331791-VPS-0-0E0-0002-N2	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega 22.5Fr 15mm - REF: 8287-18 - Basic UDI: 7331791-VPS-0-0E0-0002-N2	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega XtraSeal 17Fr 4mm - REF: 8288-18 - Basic UDI: 7331791-VPS-0-0E0-0004-N8	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega XtraSeal 17Fr 6mm - REF: 8289-18 - Basic UDI: 7331791-VPS-0-0E0-0004-N8	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega XtraSeal 17Fr 8mm - REF: 8290-18 - Basic UDI: 7331791-VPS-0-0E0-0004-N8	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega XtraSeal 17Fr 10mm - REF: 8291-18 - Basic UDI: 7331791-VPS-0-0E0-0004-N8	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega XtraSeal 17Fr 12.5mm - REF: 8292-18 - Basic UDI: 7331791-VPS-0-0E0-0004-N8	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega XtraSeal 17Fr 15mm - REF: 8293-18 - Basic UDI: 7331791-VPS-0-0E0-0004-N8	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega XtraSeal 20Fr 4mm - REF: 8294-18 - Basic UDI: 7331791-VPS-0-0E0-0004-N8	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega XtraSeal 20Fr 6mm - REF: 8295-18 - Basic UDI: 7331791-VPS-0-0E0-0004-N8	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega XtraSeal 20Fr 8mm - REF: 8296-18 - Basic UDI: 7331791-VPS-0-0E0-0004-N8	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega XtraSeal 20Fr 10mm - REF: 8297-18 - Basic UDI: 7331791-VPS-0-0E0-0004-N8	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega XtraSeal 20Fr 12.5mm - REF: 8298-18 - Basic UDI: 7331791-VPS-0-0E0-0004-N8	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega XtraSeal 20Fr 15mm - REF: 8299-18 - Basic UDI: 7331791-VPS-0-0E0-0004-N8	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega XtraSeal 22.5Fr 4mm - REF: 8300-18 - Basic UDI: 7331791-VPS-0-0E0-0004-N8	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega XtraSeal 22.5Fr 6mm - REF: 8301-18 - Basic UDI: 7331791-VPS-0-0E0-0004-N8	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega XtraSeal 22.5Fr 8mm - REF: 8302-18 - Basic	IIb	N/A	41310296-04 Intertek (0413)

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
UDI: 7331791-VPS-0-0E0-0004-N8 Devicename:Provox Vega XtraSeal 22.5Fr 10mm - REF: 8303-18 - Basic UDI: 7331791-VPS-0-0E0-0004-N8	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega XtraSeal 22.5Fr 12.5mm - REF: 8304-18 - Basic UDI: 7331791-VPS-0-0E0-0004-N8	IIb	N/A	41310296-04 Intertek (0413)
Devicename:Provox Vega XtraSeal 22.5Fr 15mm - REF: 8305-18 - Basic UDI: 7331791-VPS-0-0E0-0004-N8	IIb	N/A	41310296-04 Intertek (0413)

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive: NA

Device name and 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 device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/05/04	C694714	Initial issue
2025/02/13	C694714	Removal of devices: Provox LaryTube Sizer Kit & Provox LarryButton Sizer Kit

Lack of fulfilment of conditions

The following may render this letter of confirmation invalid:

- Lack of compliance to the requirements of Regulation (EU) 2023/607.
- Significant changes to design or intended purpose of the devices.
- Changes in the quality system affecting production.
- Periodical audits not held within the timeframe.