Add value.
Inspire trust.

TÜV SÜD Product Service GmbH· Ridlerstr. 65 · 80339 Munich · Germany

PARI GmbH,
Spezialisten für effektive Inhalation
Moosstr. 3
82319 Starnberg
GERMANY

Your reference/letter of	Our reference/name	E-mail	Tel. extension	Date	Page
011861	713329282	medical_devices@tuvsud.com	---	2024-08-13	1 of 6

TÜV SÜD Product Service GmbH
Confirmation Letter

CL 011861 0632 Rev. 00

Reference: 713181777 | 713234576 | 713223142 | 713329282

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 (in the following referenced as MDR) as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

With this letter TÜV SÜD Product Service GmbH, designated under MDR and identified by the number 0123 on NANDO, confirms that we have 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 above stated manufacturer with the following SRN Number:

SRN Number: DE-MF-000006567

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 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 TÜV SÜD Product Service GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

If 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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that: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 or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively.

The transition timelines in accordance Article 120 (3) of MDR 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, 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 (except 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, 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)

The issuance of the first confirmation letter is free of charge. We reserve the right to invoice further copies, amendments and / or changes of the confirmation letter according to effort.

For confirmation letter validity see: www.tuvsud.com/ps-cert?q=cert:CL 011861 0632 Rev. 00

In case of inquiries please contact: medical_devices@tuvsud.com

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-08-13

TÜV SÜD Product Service GmbH
Medical and Health Services

Gabriela Teodora Rusu
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Konrad Fackler
Application Reviewer

Table 1: Devices covered by this letter and for which 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 during application review)	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
Child Mask PP (Type 014) 014E1502 **Adult Mask PP (Type 012)** 012E1722	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 011861 0076 Rev. 02 NB# 0123
Child Mask LCD (PVC) **Adult Mask LCD (PVC)** **(Type 014)** 014E2011 014E2012	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 011861 0076 Rev. 02 NB# 0123
PARI PEP S System **(Type 018)** 018B4000 018G4005	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 011861 0076 Rev. 02 NB# 0123
PARI LC Family **(Type 022)** **(PARI LC, PARI LC PLUS/Turbo/Junior, PARI BABY, PARI LC STAR, PARI LC D, PARI LC D SINUS)** 022B0210, 022G8722, 022G8728, 022G8732, 022G8781	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 011861 0076 Rev. 02 NB# 0123
PARI LC SPRINT Family **(Type 023)** **(PARI LC SPRINT, PARI LC SPRINT Junior, PARI LC SPRINT COMPACT, PARI LC SPRINT BABY, PARI LC SPRINT STAR, PARI LC SPRINT Tracheo, PARI LC SPRINT Central, PARI LC SPRINT SP, PARI LC SPRINT SP BABY, PARI LC SPRINT SINUS, PARI LC SPRINT XLent, (including Sputum trap, LC interrupter, LC stand))** 023B1400, 023B1500, 023B1501, 023B1520, 023B1580, 023B1581, 023B1600, 023B1800, 023G1005, 023G1008, 023G1010, 023G1013, 023G1026, 023G1105, 023G1120,	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 011861 0076 Rev. 02 NB# 0123

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
023G1126, 023G1206, 023G1255, 023G1400, 023G1401, 023G1402, 023G1403, 023G1801, 023G1805, 023G2800, 023G2805, 023G2860, 023G2865, 023G3021, 023G3810, 023G3811, 023G3816, 023G6015, 023G6016, 023G6110, 023G6116, 023G6140, 023G6150, 023G8028, 023G8180, 023G8181			
PARI SINUS (Type 028) 028B1018	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 011861 0076 Rev. 02 NB# 0123
PARI Frog Mask **PARI Ladybug Mask (Type 041)** 041E0712, 041G0712, 041E0714, 041G0714	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 011861 0076 Rev. 02 NB# 0123
PARI SMARTMASK (Type 041) 041E0730 041B0730 041G0730	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 011861 0076 Rev. 02 NB# 0123
PARI BOY mobile S (Type 047) 047B1010	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 011861 0076 Rev. 02 NB# 0123
PARI BASIC (Type 047) 047B3010	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 011861 0076 Rev. 02 NB# 0123
VELOX, PARI BOY free (Type 055) 055G1001, 055G1004, 055G1006, 055G1200, 055G3010, 055G3210, 055G1012	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 011861 0076 Rev. 02 NB# 0123
PARI NaCl Inhalation Solution (Type 077) 077G0001	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: Certificate # G1 011861 0076 Rev. 02 NB# 0123

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
MucoClear 3% (Type 077) 077G5010 077G5013 077G5001	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: Certificate # G1 011861 0076 Rev. 02 NB# 0123
PARI BOY SX (Type 085) 085B3040 085B3200	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 011861 0076 Rev. 02 NB# 0123
PARI OEM Compressor (Type 085) 085B2010	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 011861 0076 Rev. 02 NB# 0123
PARI OEM Baby Mask (Type 100) 041E0782	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 011861 0076 Rev. 02 NB# 0123
PARI SINUS2 (Type 128) 128B1000, 128B1002, 128B1005, 128B1006, 128B1009	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 011861 0076 Rev. 02 NB# 0123
PARI BOY (Type 130) 130B1006, 130B1026, 130B1046, 130G1236	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 011861 0076 Rev. 02 NB# 0123
PARI COMPACT2 (Type 152) 152B1006	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 011861 0076 Rev. 02 NB# 0123
OEM Compressor (Type 430) 430B1006	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 011861 0076 Rev. 02 NB# 0123

Table 2: Devices covered by this letter and for which 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 during application review)	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
Not applicable	☒ N/A	☒ N/A	☒ N/A

Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024-08-13	713329282	Initial issue