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

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Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
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TÜV SÜD Product Service GmbH
Confirmation Letter
CL 054875 0007 Rev. 00

Reference: 713303068 | 713181416 | 713220410 | 713305625

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: CH-MF-000016749
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.
- N/A: 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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that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)

We reserve the right to invoice any issuance, 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 054875 0007 Rev. 00

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

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
22.03.2024

TÜV SÜD Product Service GmbH
Medical and Health Services

Eva Schaeffer
Eva Schaeffer (25. März 2024 08:12 GMT+1)

Eva Schaeffer
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Arianit Fazlija
2024.03.23 11:20:34 +01'00'

Arianit Fazlija
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
ServoPen Fix	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ Identification of the corresponding device under MDD/AIMDD Individual Article number: 700008486, 700008487	☒ Certification as follows: Certificate # G1 054875 0003 Rev. 00; NB# 0123
(ServoPen Fix) Terrosa Pen	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ Identification of the corresponding device under MDD/AIMDD Individual Article number: 700008486	☒ Certification as follows: Certificate # G1 054875 0003 Rev. 00; NB# 0123
(ServoPen Fix) Movymia Pen	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ Identification of the corresponding device under MDD/AIMDD Individual Article number: 700008487	☒ Certification as follows: Certificate # G1 054875 0003 Rev. 00; NB# 0123
YpsoPen Twist	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa	☒ Identification of the corresponding device under MDD/AIMDD Individual Article number: 700022753	☒ Certification as follows: Certificate # G1 054875 0003 Rev. 00; 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
	☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		
Polhumin Pen	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ Identification of the corresponding device under MDD/AIMDD Individual Article number: 700000641	☒ Certification as follows: Certificate # G1 054875 0003 Rev. 00; NB# 0123
• YpsoPump Orbit soft Infusion set **• YpsoPump Orbit micro Infusion set** **• Orbit soft Universal Infusion Set Cannula** **• Orbit micro Universal Infusion Set Cannula**	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ Identification of the corresponding device under MDD/AIMDD Individual Article number: MYOYP1861 MYOYP1851, MYOYP2451, MYOYP3151, MYOYP4351, MYOYP1881, MYOYP2481, MYOYP3181, MYOYP4381 OYP1006, OYP1009 OYP1005, OYP1008	☒ Certification as follows: Certificate # G1 054875 0003 Rev. 00; NB# 0123
• Orbit soft Infusion Sets **• Orbit micro Infusion Sets** **• Orbit soft Infusion Set Cannula** **• Orbit micro Infusion Set Cannula** **• Soft-Release-O Infusion Set** **• Soft-Release Micro Infusion Set**	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ Identification of the corresponding device under MDD/AIMDD Individual Article number: O2461, O3061, O2491, O3091, O4291, O4291OB O2451, O3051, O2481, O4271, O3081 O1006, O1009 O1005, O1008 S3061, S6061, S8061, S3091, S6091, S8091 S3051, S6051, S8051, S3081, S6081, S8081	☒ Certification as follows: Certificate # G1 054875 0003 Rev. 00; NB# 0123
• YpsoPump Orbit soft Extended Infusion Set	☐ Class III ☐ Class IIb implantable (non-exempted)	☒ Identification of the corresponding device under MDD/AIMDD	☒ Certification as follows: Certificate # G1 054875 0003 Rev. 00; 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
• YpsoPump Orbit micro Extended Infusion Set **• YpsoPump Orbit soft Extended Infusion Set Cannula** **• YpsoPump Orbit micro Extended Infusion Set Cannula**	☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	Individual Article number: MYOYP1862, MYOYP2462, MYOYP3162, MYOYP4362, MYOYP1892, MYOYP2492, MYOYP3192, MYOYP4392 MYOYP1852, MYOYP2452, MYOYP3152, MYOYP4352, MYOYP1882, MYOYP2482, MYOYP3182, MYOYP4382 OYP2006, OYP2009 OYP2005, OYP2008	
YpsoPump Reservoir	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ Identification of the corresponding device under MDD/AIMDD Individual Article number: 700001181, 700013320, 700001182	☒ Certification as follows: Certificate # G1 054875 0003 Rev. 00; NB# 0123
YpsoPump	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ Identification of the corresponding device under MDD/AIMDD Individual Article number: 700009374, 700009384, 700009420, 700009421, 700009422, 700009423, 700009425, 700009431, 700009432, 700009433, 700009434, 700009437, 700009438, 700012342, 700012540, 700013497, 700013501, 700013502, 700013504, 700014568, 700015151, 700015646, 700018023, 700019416	☒ Certification as follows: Certificate # G1 054875 0003 Rev. 00; NB# 0123
Clickfine	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition	☒ Identification of the corresponding device under MDD/AIMDD Individual Article number: 700000481,700009663, 700000482,700000483, 3200927,3200928,3200923, 700009649, 3200432, 3200433,	☒ Certification as follows: Certificate # G1 054875 0003 Rev. 00; 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
	☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	3200434, 3200435, 3200953, 700009650, 3200954, 3200955, 3200956, 3200957, 700000937, 700009681,700000942, 00000943,3200924, 700010323, 3200925, 3200926, 700007933, 700012293,700007934, 700007935,7000223025, 700023039,700023040, 700023041, 700023044	
Penfine Classic	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: 3300001, 700009706, 3300002, 3300003, 3300007, 700009710, 3300008, 3300009	☒ Certification as follows: Certificate # G1 054875 0003 Rev. 00; NB# 0123
Optifine	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ Identification of the corresponding device under MDD/AIMDD Individual Article number: 3100933,3100934,3100935, 3100936	☒ Certification as follows: Certificate # G1 054875 0003 Rev. 00; NB# 0123
Clickfine AutoProtect	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ Identification of the corresponding device under MDD/AIMDD Individual Article number: 700001154, 3110111	☒ Certification as follows: Certificate # G1 054875 0003 Rev. 00; NB# 0123

Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024/03/22	713303068, 713181416, 713220410, 713305625	Initial issue