



TÜV SÜD Product Service GmbH

Your reference/letter of	Our reference/name	Tel. extension/Email	Date	Page
110550_v1_MDRAPP_VerityMedicalIRE	TPS0343 PSE1722492	Michael.Gravestock@TUVSUD.com	2024-04-16	1 of 2

Receipt of formal application

Reference: 110550_v1_MDRAPP_VerityMedicalIRE

To whom it may concern,

Confirmation of the status of a formal application 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 with the above stated manufacturer with the following SRN Number:

SRN Number: IE-MF-000007426

The devices covered by the formal application mentioned above are identified in the Table below.

Please note that this letter only confirms the status of the formal application.

To benefit from the additional transitional provisions in the framework of Regulation EU 2023/607, TÜV SÜD Product Service GmbH and the manufacturer need to sign a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR latest until 26 September 2024.

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

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
15 May 2024

TÜV SÜD Product Service GmbH
Medical and Health Services

Michael Gravestock

[Michael Gravestock \(May 15, 2024 16:46 GMT+1\)](#)

Michael Gravestock
Conformity Assessment Responsible (CARE)



Devices covered by the formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR

Device name or Basic UDI-DI (under MDR application)
Device 1: 506007397ECS300AZ5 NeuroTrac Universal Tens
Device 2 506007397ECS310AZA NeuroTrac Obstetric
Device 3 506007397ECS305AZL NeuroTrac REHAB
Device.4 506007397ECS831XP NeuroTrac Primera
Device 5 506007397OPH3104V Kegel8 Mother Nature
Device 6 506007397C6V350SR NeuroTrac MultiTens Zimmer MultiTens
Device 7 506007397ECS400AZC NeuroTrac CONITINENCE
Device 8 506007397OPH4004X Kegel8 Tight & Tone
Device 9 506007397ECS401AZF NeuroTrac Sports
Device 10 506007397ETS2014E NeuroTrac Sports XL
Device 11 506007397OPH2024R Kegal8 Ultra 20
Device 12 506007397ETS2004C NeuroTrac PelviTone Kegel8 Ultra
Device 13 506007397OPH22555 Kegel8 V for Men
Device 14 506007397IFC184WE NeuroTrac IFC Rehab
Device 15 506007397MYO120PDU NeuroTrac MyoPLus Pro
Device 16 506007397MYO24PAR NeuroTrac MyoPlus 2 Pro NeuroTrac MyoPlus 4 Pro
Device 17 506007397OPH120P8U Kegel8 MultiTone