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|  | Quality Form                 | Form:<br>F.A04.07(DOC).02/03.23 |
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| DOC ID:<br>DOC ID:                                                                                                                                                            | F.A04.07(DOC)-201-03 |                                                                                                                                                                                                                                                                                                                            | <br><br><b>EU KONFORMITÄTSERKLÄRUNG /<br/>EU DECLARATION OF CONFORMITY</b> |  |
| Name und Adresse der Firma:<br>Name and address of the Firm:                                                                                                                  |                      | MTR plus Vertriebs GmbH,<br>Kamenzer Damm 80, 12249 Berlin, Germany.                                                                                                                                                                                                                                                       |                                                                                                                                                              |  |
| Single Registration Number (SRN):                                                                                                                                             |                      | DE-MF-000006445                                                                                                                                                                                                                                                                                                            |                                                                                                                                                              |  |
| <p align="center"><b>Wir erklären in alleiniger Verantwortung, dass</b><br/><b>We declare under our sole responsibility that:</b></p>                                         |                      |                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                              |  |
| das Medizinprodukt:<br>the medical device(s):                                                                                                                                 |                      | 010E-201 Rehalito Device                                                                                                                                                                                                                                                                                                   |                                                                                                                                                              |  |
| mit dem Verwendungszweck:<br>with the intended Purpose:                                                                                                                       |                      | Digitales STIM (Neuromuskuläre Stimulation) zur<br>Muskelrehabilitation.<br>Digital STIM (Neuromuscular Stimulation) for muscle<br>rehabilitation.                                                                                                                                                                         |                                                                                                                                                              |  |
| entsprechend dem Ausgabestand der<br>technischen Dokumentation:<br>according to the technical documentation:                                                                  |                      | Technischer Ordner: L.A02.01(DMR)-201-01-00<br>Technical File: L.A02.01(DMR)-201-01-00                                                                                                                                                                                                                                     |                                                                                                                                                              |  |
| mit der Basis-UDI-DI:<br>with basic UDI-DI:                                                                                                                                   |                      | 0426027958STIMULATIONUP                                                                                                                                                                                                                                                                                                    |                                                                                                                                                              |  |
| mit der EMND:<br>with EMND:                                                                                                                                                   |                      | Z12069080                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                              |  |
| der Klasse:<br>Of Class:                                                                                                                                                      | Ila                  | Gemäß Anlage VIII der MDR 2017/745 – Regel:<br>According to annex VIII of MDR 2017/745 – Rule:                                                                                                                                                                                                                             | 9                                                                                                                                                            |  |
| <p align="center"><b>allen Anforderungen der MDR 2017/745 entspricht, die anwendbar sind.</b><br/><b>Meet all the provisions of the MDR 2017/745 which apply to them.</b></p> |                      |                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                              |  |
| Konformitätsbewertungsverfahren:<br>Conformity assessment procedure:                                                                                                          |                      | Anhang IX Kapitel I und III.<br>Annex IX chapters I and III.                                                                                                                                                                                                                                                               |                                                                                                                                                              |  |
| Angewandte Spezifikationen und<br>Normen:<br>Applied specifications and standards:                                                                                            |                      | Beachten Sie Anhang II mit der Liste der angewandten<br>Normen. Für diese Geräte wurden keine gemeinsamen<br>Spezifikationen (CS) verwendet.<br>Observe Annex II with the list of applied standards. No<br>common specifications (CS) have been used for these devices.                                                    |                                                                                                                                                              |  |
| Benannte Stelle:<br>Notified Body:                                                                                                                                            |                      | TÜV SUD Product Service GmbH,<br>Ridlerstraße 65, 80339 München, Germany<br>CE0123                                                                                                                                                                                                                                         |                                                                                                                                                              |  |
| Zertifikatsnummer:<br>Certificate Number:                                                                                                                                     |                      | G10 048742 0017 Rev. 00                                                                                                                                                                                                                                                                                                    |                                                                                                                                                              |  |
| Gültigkeit der Erklärung:<br>Declaration Validity:                                                                                                                            |                      | Gültig bis zum 05.12.2028.<br>Valid until 05.12.2028                                                                                                                                                                                                                                                                       |                                                                                                                                                              |  |
| Ort, Datum / Place & Date:<br><br>Berlin, 10/03/2025                                                                                                                          |                      | General Manager MTR plus Vertriebs GmbH<br>Bereich / Funktion<br><br><br>Kamenzer Damm 80, 12249 Berlin<br>Tel. 030 / 66 99 10 30, Fax 66 99 10 35 |                                                                                                                                                              |  |

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Approved by M. Liewehr  
Validated by P. Liewehr

Issue Date: 01/03/2023

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#### Annex I – Photos



#### Annex II – Specifications and standards.

ISO 13485:2016/A11:2021, EN 14971:2019/A11:2021, IEC 60601-1:2020, IEC60601-1-2:2020, IEC 60601-2-10:2016, IEC 60601-1-11:2020, IEC 60601-1-6:2020, IEC 62366-1:2020, EN ISO 20417:2021, ISO 15223-1:2021, IEC 62304:2015, ISO 10993-1:2020, ISO 10993-18:2020, ISO 10993-5:2009, ISO 10993-10:2021.