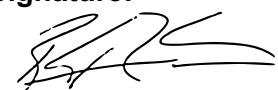


## DECLARATION OF CONFORMITY

In accordance with Council Directive 93/42/EEC amendment 2007/47/EEC

|                                                                                                                                                                                                                                                         |                                                                                                                                 |                                                                                                            |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------|
| <b>DEVICES</b>                                                                                                                                                                                                                                          |                                                                                                                                 |                                                                                                            |
| <b>XT-46000</b>                                                                                                                                                                                                                                         | STIMPOD NMS410 Peripheral Nerve Stimulator                                                                                      |                                                                                                            |
| <b>KITS</b>                                                                                                                                                                                                                                             |                                                                                                                                 |                                                                                                            |
| <b>XT-46001</b>                                                                                                                                                                                                                                         | STIMPOD NMS460 Peripheral Nerve Stimulator Kit                                                                                  |                                                                                                            |
| <b>ACCESSORIES</b>                                                                                                                                                                                                                                      |                                                                                                                                 |                                                                                                            |
| <b>XT-41002</b>                                                                                                                                                                                                                                         | Carry Case                                                                                                                      |                                                                                                            |
| <b>XT-41007</b>                                                                                                                                                                                                                                         | IV Pole Mount                                                                                                                   |                                                                                                            |
| <b>XT-46003</b>                                                                                                                                                                                                                                         | STIMPOD NMS460 Nerve Mapping Cable                                                                                              |                                                                                                            |
| <b>MANUFACTURER</b>                                                                                                                                                                                                                                     |                                                                                                                                 |                                                                                                            |
| <b>Name</b>                                                                                                                                                                                                                                             | Xavant Technology (Pty) Ltd                                                                                                     |                                                                                                            |
| <b>Address</b>                                                                                                                                                                                                                                          | 102 Tannery Industrial Park, 309 Derdepoort Road, Silverton, Pretoria, 0184, South Africa                                       |                                                                                                            |
| <b>QMS Contact</b>                                                                                                                                                                                                                                      | W Kennedy, Email: compliance@xavant.com                                                                                         |                                                                                                            |
| <b>EC REPRESENTATIVE</b>                                                                                                                                                                                                                                |                                                                                                                                 |                                                                                                            |
| <b>Name</b>                                                                                                                                                                                                                                             | Emergo Europe                                                                                                                   |                                                                                                            |
| <b>Address</b>                                                                                                                                                                                                                                          | Prinsessegracht 20, 2514 AP The Hague, The Netherlands                                                                          |                                                                                                            |
| <b>Contact</b>                                                                                                                                                                                                                                          | Phone:+31.70.345.8570, Fax:+31.70.346.7299, Email: europe@emergogroup.com                                                       |                                                                                                            |
| <b>CONFORMITY ASSESSMENT</b>                                                                                                                                                                                                                            |                                                                                                                                 |                                                                                                            |
| <b>Classification</b>                                                                                                                                                                                                                                   | Class IIa, Rule 9                                                                                                               |                                                                                                            |
| <b>Route</b>                                                                                                                                                                                                                                            | Annex II, 93/42/EEC, excluding section 4                                                                                        |                                                                                                            |
| <b>GMDN</b>                                                                                                                                                                                                                                             | <b>35729</b>                                                                                                                    | Diagnostic peripheral nerve electrical stimulation system                                                  |
| <b>NGOB</b>                                                                                                                                                                                                                                             | <b>MD1103</b>                                                                                                                   | Devices for stimulation or inhibition                                                                      |
| <b>Accreditation</b>                                                                                                                                                                                                                                    | SGS Belgium NV, Notified Body 1639                                                                                              |                                                                                                            |
| <b>Certificate</b>                                                                                                                                                                                                                                      | ES19/86843, Validity: 16 December 2019 until 26 February 2024                                                                   |                                                                                                            |
| <b>Standards</b>                                                                                                                                                                                                                                        | BS EN ISO 13485, BS EN IEC 60601-1, IEC 60601-1-2/ CISPR11 Group 1 Class A, IEC 60601-2-10, IEC 60601-2-6/IEC 62366, IEC 62304. |                                                                                                            |
| <p><b><i>We hereby declare that the above-mentioned products comply with the European Medical Device Directive 93/42/EEC-2007/47/EC and its relevant transposition into national laws of the member states into which we place the devices.</i></b></p> |                                                                                                                                 |                                                                                                            |
| <b>Approved By:</b><br>R Janse van Rensburg<br>Management Representative                                                                                                                                                                                |                                                                                                                                 | <b>Date:</b><br>22 May 2021                                                                                |
|                                                                                                                                                                                                                                                         |                                                                                                                                 | <b>Signature:</b><br> |

## Additional Statement to the Declaration of Conformity

Herewith **Xavant Technology (Pty) Ltd** declares that the following non-significant changes (in compliance with MDCG 2020-3 Rev 1) apply to the devices listed on the original Declaration of Conformity. There have been no additional devices added to the original DoC, which was issued on 22-May-2021 with Ver 08.

| CHANGE                                                                                  |                                                                                                                          |                                                                                                                                                    |                          |
|-----------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|
| Type of Change (delete from list as appropriate)                                        | Old                                                                                                                      | New                                                                                                                                                | Effective date of change |
| Change of EUAR address                                                                  | Prinsessegracht 20,<br>2514 AP The Hague,<br>The Netherlands                                                             | Westervoortsedijk 60<br>6827 AT Arnhem<br>The Netherlands                                                                                          | 26-Apr-2023              |
| Non-significant model number addition (minor software changes as per MDCG 2020-3_Rev 1) | None                                                                                                                     | XT-46000A STIMPOD NMS410<br>Peripheral Nerve Stimulator<br>Algiamed<br><br>XT-46001A STIMPOD NMS410<br>Peripheral Nerve Stimulator<br>Algiamed Kit |                          |
| Typo correction made to product description                                             | XT-46000 STIMPOD NMS410 Peripheral Nerve Stimulator<br><br>XT-46001A STIMPOD NMS410 Peripheral Nerve Stimulator Algiamed | XT-46000A STIMPOD NMS460 Peripheral Nerve Stimulator<br><br>XT-46001A STIMPOD NMS460 Peripheral Nerve Stimulator Algiamed                          | 05-Feb-2024              |
| Inclusion of Manufacturer's SRN and Basic UDI-DI                                        | None                                                                                                                     | ZA-MF-000011657<br>06009880396XT46000BF                                                                                                            |                          |
| Typo Change in GMDN Code                                                                | 35729                                                                                                                    | 35372 Analgesic transcutaneous electrical nerve stimulation system                                                                                 |                          |
| Typo Change in NBOG codes                                                               | MD1103                                                                                                                   | MD1301 Monitoring devices of non-vital physiological parameters                                                                                    |                          |
| Addition of Manufacturer's responsibility declaration statement                         | None                                                                                                                     | This is to declare that EU Declaration of Conformity is issued under the sole responsibility of the manufacturer.                                  |                          |

**COMPANY REPRESENTATIVE:** R. Janse van Rensburg

**TITLE:** CEO, Management Representative

**DATE:** 09-Feb-2024

**SIGNATURE:**

