Elliquence
Innovative Medical Solutions

# DECLARATION OF CONFORMITY

FULL QUALITY ASSURANCE SYSTEM

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| **Product Name:** | Hemo and Single Action Bipolar Footswitch, Dual Bipolar Footswitch, Triple Footswitch | |
| **Model Numbers:** | BF-FSC#, DF-FSC#, DF-FSC/3, SVF1, TF-FSC#, HB-FSC#, BF-FSCB#, TF-FSCB#, | |
| **GMDN Code:** | Remote control, foot switch [36336] | |
| **Device Classification:** | I, Rule 1 | |
| **Applied Standards:** | EN 60601-2-2:2009<br>EN ISO 15223-1:2016<br>EN 1041:2008<br>EN 60601-1:2006/A1:2013 | ISO 13485:2016<br>EN ISO 14971:2012<br>IEC 60601-1:2005/A1:2012 |
| **Manufacturer:** | ELLIQUENCE, LLC<br>2455 Grand Avenue<br>Baldwin, New York 11510<br>USA | Phone: (516) 277-9000<br>Fax: (516) 277-9001<br>Email: quality@elliquence.com |
| **EU Representative:** | EMERGO EUROPE<br>Prinsessegracht 20<br>2514 AP The Hague<br>The Netherlands | Phone: +31.70.345.8570<br>Fax: +31.70.346.7299<br>Email: service@emergogroup.com |

**Lot/Serial Number:**

***This declaration of conformity is issued under the sole responsibility of the manufacturer. The object of the declaration described above is in conformity with the relevant Community Harmonization Legislation. I hereby declare that the products specified above meet the requirements set forth in LVFS 2003:11 and Council Directive MDD 93/42/EEC, MDD Annex VII and conform to the identified harmonized standards. In addition, the object of the declaration described above is in conformity with RoHS Directive 2011/65/EU (RoHS 2) of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment. [RoHS]***

***In addition, I ensure and declare that the distributed CE marked product, as mentioned and falling within Class I, meet the provisions of the EC-Directive which apply to it.***

***This declaration is based on the application of the Quality System approved for the manufacture and final inspection of the products concerned.***

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| Alan Ellman, CEO | April 23, 2021<br>Date |