# DECLARATION OF CONFORMITY

FULL QUALITY ASSURANCE SYSTEM

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|---|---|---|
| **Product Name:** | Surgical Guidewires | |
| **Model Numbers:** | DFX-GW-S, DFX-GW-18, DFX-GW-20 | |
| **GMDN Code:** | Spinal Guidewire [63819] | |
| **Device Classification:** | IIa, Rule 6 | |
| **Applied Standards:** | EN 60601-2-2:2009<br>EN ISO 15223-1:2016<br>EN 1041:2008<br>IEC 60601-2-2:2009 | ISO 11135-1:2007<br>ISO 13485:2016<br>EN ISO 14971:2012 |
| **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 | Email: emergoeurope@ul.com |
| **Notified Body & Identification Number:** | INTERTEK SEMKO AB<br>Kista, Sweden<br>0413 | |
| **EC Certificate Number:** | 41316578-03 | |
| **Lot #:** | | |

***This declaration of conformity is issued under 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 II, excluding Section 4 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]***

Alan Ellman, CEO

April 21, 2020
Date

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