DECLARATION OF CONFORMITY

FULL QUALITY ASSURANCE SYSTEM

Product Name:	Spinal Needle	
Model Numbers:	DFX-N6; DFX-N8; DFX-N6/1; DFX-N8/1	
GMDN Code:	Guide [35150]	
Device Classification:	IIa, Rule 6	
Applied Standards:	EN ISO 15223-1:2016 EN 1041:2008+A1:2013 EN 20594-1:1993/AC:1996 ISO 594-1:1986	ISO 11135-1:2014 ISO 13485:2016 EN ISO 14971:2012 ISO 10993-1:2009
Manufacturer:	ELLIQUENCE, LLC 2455 Grand Avenue Baldwin, New York 11510 USA	 Phone: (516) 277-9000 Fax: (516) 277-9001 Email: quality@elliquence.com
EU Representative:	EMERGO EUROPE Prinsessegracht 20 2514 AP The Hague The Netherlands	 Phone: +31.70.345.8570 Fax: +31.70.346.7299 Email: service@emergogroup.com
Notified Body & Identification Number:	INTERTEK SEMKO AB Kista, Sweden 0413	
EC Certificate Number:	41316578-03	
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 II (3) 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

May 20, 2020
Date