



DECLARATION OF CONFORMITY
FULL QUALITY ASSURANCE SYSTEM

Product Name: Access Needle

Model Numbers: N6-D4, N6-D4/1, N6-D5, N6-D5/1

GMDN Code: Guide [35150]

Device Classification: IIa, Rule 6

Applied Standards: EN ISO 15223-1:2016 ISO 11135-1:2007
EN 1041:2008 ISO 13485:2016
EN ISO 14971:2012

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

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

April 21, 2020

Date