



DECLARATION OF CONFORMITY
FULL QUALITY ASSURANCE SYSTEM

Product Name: Surgi-Max Ultra

Model Numbers: IEC6-SU120, IEC6-SU170

GMDN Code: Electrosurgical system, general-purpose [44776]

Device Classification: IIb, Rule 9

Applied Standards: EN 60601-2-2:2009 IEC 60601-1:2005/A1:2012
EN ISO 15223-1:2016 IEC 60601-2-2:2009
EN 1041:2008 EN 62304:2006/AC:2008
EN 60601-1:2006+A1:2013 ISO 13485:2016
EN 60601-1-2:2015 EN ISO 14971:2012

Manufacturer: ELLIQUENCE, LLC Phone: (516) 277-9000
2455 Grand Avenue Fax: (516) 277-9001
Baldwin, New York 11510 Email: quality@elliquence.com
USA


EU Representative: EMERGO EUROPE
Prinsessegracht 20
2514 AP The Hague
The Netherlands

Notified Body & Identification Number: INTERTEK SEMKO AB
Kista, Sweden
0413

EC Certificate Number: 41316578

Serial Number: 1F130126

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

June 5, 2019
Date

elliquence, LLC.
2455 Grand Avenue • Baldwin, New York 11510
(516) 277.9000 • Fax: (516) 277.9001 • www.elliquence.com