



## DECLARATION OF CONFORMITY

### FULL QUALITY ASSURANCE SYSTEM

**Product Name:** Spinal Burr, Support Sleeve, Cutter

**Model Numbers:** 16-0102, 16-0103, 16-0104, 16-0202, 16-0203, 16-0204, 16-0205, 16-0206, 16-0207, 16-0209, 16-0211, 16-0212, 16-0213, 16-0214

**GMDN Code:** Drill, surgical, system [11329]

**Applied Standards:**

- ISO 10993-1:2009
- ISO 17664:2017
- ISO 3964:2016
- ISO 15883-1:2006
- ISO 17665-1:2006
- BS EN ISO 15223-1:2016
- ISO 13485:2016
- BS EN ISO 14971:2012
- BS EN 1041:2008+A1:2013

**Manufacturer:** ELLIQUENCE, LLC  
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**Lot Number:**

I certify, in my capacity as CEO of Elliquence, LLC that all relevant requirements of the following recognized consensus standards are met with respect to the manufacture of Elliquence products. All records relating to the manufacturers' compliance with these standards will be maintained for a period of two years or for the expected design life of the device, whichever is longer [21 USC 514(c)(3)(C)]. It is understood that these records may be subject to review during an inspection to assess conformance to the Quality System Regulation (21 CFR 820).

Alan Ellman, CEO

November 2, 2020

Date

**elliquence, LLC.**

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