



DECLARATION OF CONFORMITY
FULL QUALITY ASSURANCE SYSTEM

Product Name: Disc-FX Mini System

Model Numbers: DFXM

GMDN Code: Electrosurgical system conducting unit, foot-controlled, single-use [35703]

Device Classification: IIb, Rule 9

Applied Standards: EN ISO 14971:2012 IEC 60601-1:2005/A1:2012
 EN ISO 15223-1:2016 IEC 60601-2-2:2009
 EN 1041:2008+A1:2013 ISO 11135:2014
 EN 60601-1:2006/A1:2013 ISO 13485:2016
 ANSI/AAMI ES 60601-1:2005/R(2012)

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

EC Certificate Number: 41316578-03

Lot #:

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