



DECLARATION OF CONFORMITY
FULL QUALITY ASSURANCE SYSTEM

Product Name: 3-Button Fingerswitch Handpiece, Surg-e Pak

Model Numbers: IEC-3FHPB/D, IEC-3FHPD/D, IEC-3FHPD/D1, SP-01

GMDN Code: Electrosurgical system handpiece, hand-controlled, general-purpose, single-use [44681]

Device Classification: IIb, Rule 9

Applied Standards: EN ISO 15223-1:2016 ISO 11737-2:2009
 EN 1041:2008 ISO 13485:2016
 EN 60601-2-2:2009 EN ISO 14971:2012
 IEC 60601-2-2:2009 ISO 10993-1:2009

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Notified Body & Identification Number: INTERTEK SEMKO AB
 Kista, Sweden
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EC Certificate Number: 41316578-04

Lot/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

February 10, 2024
 Date