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Declaration of Conformity DC147	**Revision Number:** 09 **Issued:** 13-Feb-2018

Manufacturer	CareFusion France 309 S.A.S. 8 bis rue de la Renaissance 44110 Châteaubriant, France
Product	PF-IP-03: Surgical clipper
Product Codes/Scope of Application	See attached list of catalog numbers
Classification	Europe: Class I, Rule 12 Australia: Class I
GMDN Codes	See attachment

European Union Regulations:	
European Representative	N/A
We herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the following EU Council Directive(s) as transposed into national laws.	
General Applicable Directives	Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC, as amended by Directive 2007/47/EC
Annex	VII
Notified Body*	N/A
Notified Body Number*	N/A
EC Certificate*	N/A
Issued (Place/Date)*	N/A
Expires (Date)*	N/A
Quality System Certificate	EN ISO 13485 issued by TÜV SÜD Product Service GmbH: Certificate Q2N 17 01 77424 007
Expires (Date)	29-May-2020
Other Applicable Directives**	RoHS Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on restriction of the use of certain hazardous substances in electrical and electronic equipment

Australian Regulations:

This declaration is made in accordance with the requirements of Clause 6.6 of Schedule 3 of the Australian **Therapeutic Goods (Medical Devices) Regulations 2002** relating to the stated devices.

Standards Applied:
EN ISO 13485: 2012 + AC: 2012 Medical Devices – Quality Management Systems – Requirements for regulatory purposes

All supporting documentation is retained at the premises of the manufacturer.

Authorized Signatory:

Name	**Date and Place**
Yves Després Senior Director Regulatory Affairs Europe/EMA	15 Feb 2018 8 bis rue de la Renaissance 44110 Châteaubriant, France

* Not applicable to Class I self-certified devices
** Only applicable to electrical and electronic Medical Devices

This schedule is an attachment to Declaration of conformity **DC147 - REV09**
Surgical Clipper and associated charging adapter and blades
PF-IP-03

Catalog No.	Specific GMDN code	Description	First Lot Number of CE Marked Products
4406	63267	General Purpose Surgical Blade (single use)	0206
4403A	63267	Specialty Purpose Sensi Clip Surgical Blade (single use) (Gynecology, urology)	0407
4412A	63267	Specialty Purpose Surgical Blade (single use) (scalp and other thick, coarse hair)	0206
5513E	35097	Surgical Clipper	0713
5514E	35097	Charging adapter (Europe) – to be used with 5513E only	1013
5514K	35097	Charging adapter (AUS/NZ) – to be used with 5513E only	1213
5514U	35097	Charging adapter (UK) – to be used with 5513E only	0813

Clippers and Charging Adapters are labeled in the following languages:
English, French, German, Italian, Spanish, Dutch, Danish, Finnish, Greek, Norwegian, Swedish
Portuguese, Turkish, Polish, Czeck

GMDN INDEX

Clipper, hair, electric (35097)
A hand-held electrically-powered device designed for removing long hair from the head or body of a patient prior to surgery/treatment. The device is typically operated by a healthcare professional.
This is a reusable device.

Surgical hair clippers blade (63267)
A non-sterile cutting component of powered surgical hair clippers designed for removal of long hair from the head or body of a patient prior to surgery/treatment. It is typically designed as a small cartridge-like device with integrated shearing blades intended to be attached to the powered handpiece. This is a single-use device.