SuperSeton

EC DECLARATION OF CONFORMITY

We,

Super Seton B.V., Amsterdam Health Technology Centre, Wing 5D, Paasheuvelweg 25, 1105 BP Amsterdam, The Netherlands

hereby declare under our sole responsibility that the CE marked product to which this declaration relates,

SuperSeton

Sterile seton drain for the treatment of perianal fistula.

has been classified as Class IIa sterile, according to Annex IX, rule 7, and is in conformity with the essential requirements and provisions of the Council Directive 93/42/EEC concerning medical devices as amended by Directive 2007/47/EC and is in conformity with the relevant harmonised standards:

Specific Harmonized Standards for EC Declaration of Conformity	
Number	Title
EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971:2012	Medical devices - Application of risk management to medical devices
ISO 11137:2015	Sterilization of health care products - Radiation
EN 1041:2008	Information supplied by the manufacturer of medical devices
ISO 15223-1:2016	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied
ISO 11607:2006	Packaging for terminally sterilized medical devices
EN ISO 10993-1:2009	Biological evaluation of medical devices - Part 1: Evaluation and testing

and is subject to the procedure set out in Annex *V* of the Council Directive 93/42/EEC as amended by Directive 2007/47/EC.

This declaration is made on base of the quality assurance certificate
No. BE18/819943244
delivered by Notified Body no. 1639, SGS Belgium nv.

Name: W. Nerkens
Function: CTO, Quality manager
Date: 12/2018