EC DECLARATION OF CONFORMITY

6.18 Declaration of Conformity

The EC declaration of conformity will be signed before the product is placed on the market and may be referred to in the Quality Document Management system as follows:

Document number	Document Title	Content
PLURADOC-3	Declaration of conformity	The **EC declaration of conformity** is the written statement and the single declaration drawn up by the manufacturer to demonstrate the fulfilment of the EU requirements relating to a product bearing the CE marking he has manufactured. The declaration is in respect of all Community acts applicable to the product containing all information required for the identification of Community harmonisation legislation to which the declaration relates.

The following standards and regulations were applied in the documents related to this section:

Directive / Guideline	Title
EU MDR 2017/745	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices
MEDDEV 2.4/1 rev 9	Classification of Medical Devices

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This declaration of conformity is issued under the sole responsibility of Speciality Fibres and Materials Ltd.

Legal Manufacturer:	Specialty Fibres and Materials Ltd Galaxy House – 31 Herald Way, Binley Industrial Estate, CV3 2RQ, Coventry, United Kingdom
SRN:	GB-MF-000004153
Intended Use:	Suprasorb A Pro Reinforced Calcium Alginate Wound Dressings / Packing Rope can be used for the treatment of acute and chronic wounds.
General Product Name/s:	Suprasorb A Pro
Variants:	As per Annex I – Product Listing
Applicable Standards:	As Per Annex II
Classification:	Class IIb - Rule 4
EMDN Code/Term:	M040402 - Dressings, Alginate
Basic UDI-DI:	506078698CATB
Conformity Assessment Procedure:	Speciality Fibres and Materials Ltd., hereby declares that the medical devices listed on the attached Product Schedule conform to the EU Medical Device Regulation 2017/745 and are in accordance with Annex IX Conformity Assessment Procedure.
Notified Body:	BSI Group The Netherlands B.V. (CE 2797) Say Building John M. Keynesplein 9 1066 EP Amsterdam, The Netherlands
Authorised Representative:	Advena Ltd Tower Business Centre, 2nd Floor, Tower Street, Swatar, BKR 4013 Malta
EC Certificate Number:	MDR 744264
Start of CE-Marking:	12.05.2022

Signature: 

Date and Place: 12 May 2022, Coventry

Name: Nyerngoor Korda Hewitt

Position: Director of RAQ

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ANNEX I – Product Listing

Commercial Name	Product Code	Description
Suprasorb A Pro	33932	120, 5x5cm
Suprasorb A Pro	33933	120, 10x10cm
Suprasorb A Pro	33934	120, 10x20cm
Suprasorb A Pro	33935	120, 2x45cm rope
Suprasorb A Pro	33811	200, 5x5cm
Suprasorb A Pro	33812	200, 10x10cm
Suprasorb A Pro	33813	200, 10x20cm
Suprasorb A Pro	33814	200, 2x45cm rope
Suprasorb A Pro	103811	200, 5x5cm
Suprasorb A Pro	103812	200, 10x10cm

ANNEX II – List of Standards

This present declaration is also in conformity with the following European standards and Common Specifications:

Number	Standards Title	Version
EN ISO 11137-1	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	2006/A1: 2013 / 2015
EN ISO 11137-2	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose	2013 / 2015
EN ISO 11137-3	Sterilization of health care products - Radiation - Part 3: Guidance on dosimetric aspects	2017
EN ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	2009/ AC:2010
EN ISO 10993-3	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	2014

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EN ISO 10993-5	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	2009
EN ISO 10993-6	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation	2016
EN ISO 10993-10	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	2013
EN ISO 10993-11	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity	2009
EN ISO 10993-12	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials	2012
EN ISO 10993-17	Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances	2002
EN ISO 10993-18	Biological evaluation of medical devices - Part 18: Chemical characterization of materials	2005 / 2009
EN ISO 11607-1	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems	2009 / 2019
EN ISO 11607-2	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes	2006 / 2019
EN ISO 11737-1	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products	2006 / 2018
EN ISO 11737-2	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process	2009 / 2020
EN ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes	2016

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EN ISO 14155	Clinical investigation of medical devices for human subjects - Good clinical practice	2011
EN ISO 13726-1	Test methods for primary wound dressings - Part 1: Aspects of absorbency	2002 + AC:2003
EN ISO 14971	Medical devices - Application of risk management to medical devices	2019
EN ISO 15223-1	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	2016
ASTM D 4169-16	Standard Practice for Performance Testing of Shipping Containers and Systems	2016
ASTM F1980-16	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices	2016
EN 556-1	Sterilization of medical devices. Requirements for medical devices to be designated "STERILE" Requirements for terminally sterilized medical devices	2001
EN 1041	Information supplied by the manufacturer of medical devices	2008
EN 62366-1	Medical devices — Part 1: Application of usability engineering to medical devices	2015
EN 62366-2	Medical devices — Part 2: Guidance on the application ofusability engineering to medical devices	2016
EN ISO 14644-1	Cleanrooms and associated controlled environments. Classification of air cleanliness	2015
EN ISO 14644-2	Cleanrooms and associated controlled environments. Specifications for testing and monitoring to prove continued compliance with ISO 14644-1	2015