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
MCYRADOC-7	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
Council Directive 93/42/EEC	14 June 1993 concerning medical devices
MEDDEV 2.4/1 rev 9	Classification of Medical Devices

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

EC DECLARATION OF CONFORMITY

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 Liquacel Pro Wound Dressings / Packing Rope can be used for the treatment of acute and chronic wounds
General Product Name/s:	Suprasorb Liquacel Pro
Variants:	As per Annex I – Product Listing
Applicable Standards:	As Per Annex II
Classification:	Class IIb - Rule 4
EMDN Code/Term:	N/A
Basic UDI-DI:	N/A
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 Directive 93/42/EEC as amended by Directive 2007/47/EC and are in accordance with Annex II Conformity Assessment Procedure
Notified Body:	BSI Group The Netherlands B.V. (CE2797) 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:	MDD 620062
Start of CE-Marking:	8th June 2015

Signature: 

Date and Place: 01.12.2023 Coventry
Name: Nyerngoor Korda Hewitt
Position: Director of Regulatory Affairs and Quality

EC DECLARATION OF CONFORMITY

ANNEX I – Product Listing

Product Models (Commercial Names (Brands))	Product Reference	Product Variants (Commercial Names/ Dimensions)
Suprasorb Liquacel Pro	FM001018	Suprasorb Liquacel Pro 120 10x10cm
Suprasorb Liquacel Pro	FM001021	Suprasorb Liquacel Pro 120 10x12.5cm
Suprasorb Liquacel Pro	FM001022	Suprasorb Liquacel Pro 120 10x12cm
Suprasorb Liquacel Pro	FM001023	Suprasorb Liquacel Pro 120 10x20cm
Suprasorb Liquacel Pro	FM001024	Suprasorb Liquacel Pro 120 15x15cm
Suprasorb Liquacel Pro	FM001025	Suprasorb Liquacel Pro 120 15x20cm
Suprasorb Liquacel Pro	FM001026	Suprasorb Liquacel Pro 120 1x30cm
Suprasorb Liquacel Pro	FM001027	Suprasorb Liquacel Pro 120 1x45cm
Suprasorb Liquacel Pro	FM001028	Suprasorb Liquacel Pro 120 20x20cm
Suprasorb Liquacel Pro	FM001029	Suprasorb Liquacel Pro 120 20x30cm
Suprasorb Liquacel Pro	FM001030	Suprasorb Liquacel Pro 120 2x30cm
Suprasorb Liquacel Pro	FM001031	Suprasorb Liquacel Pro 120 2x45cm
Suprasorb Liquacel Pro	FM001032	Suprasorb Liquacel Pro 120 4x10cm
Suprasorb Liquacel Pro	FM001033	Suprasorb Liquacel Pro 120 4x20cm
Suprasorb Liquacel Pro	FM001034	Suprasorb Liquacel Pro 120 4x30cm
Suprasorb Liquacel Pro	FM001035	Suprasorb Liquacel Pro 120 5x5cm
Suprasorb Liquacel Pro	FM001019	Suprasorb Liquacel Pro 160 10x10cm
Suprasorb Liquacel Pro	FM001067	Suprasorb Liquacel Pro 160 10x10cm
Suprasorb Liquacel Pro	FM001036	Suprasorb Liquacel Pro 160 10x12.5cm
Suprasorb Liquacel Pro	FM001037	Suprasorb Liquacel Pro 160 10x12cm
Suprasorb Liquacel Pro	FM001038	Suprasorb Liquacel Pro 160 10x20cm
Suprasorb Liquacel Pro	FM001039	Suprasorb Liquacel Pro 160 15x15cm
Suprasorb Liquacel Pro	FM001040	Suprasorb Liquacel Pro 160 15x20cm
Suprasorb Liquacel Pro	FM001041	Suprasorb Liquacel Pro 160 1x30cm
Suprasorb Liquacel Pro	FM001042	Suprasorb Liquacel Pro 160 1x45cm
Suprasorb Liquacel Pro	FM001043	Suprasorb Liquacel Pro 160 20x20cm

EC DECLARATION OF CONFORMITY

Suprasorb Liquacel Pro	FM001044	Suprasorb Liquacel Pro 160 20x30cm
Suprasorb Liquacel Pro	FM001045	Suprasorb Liquacel Pro 160 2x30cm
Suprasorb Liquacel Pro	FM001046	Suprasorb Liquacel Pro 160 2x45cm
Suprasorb Liquacel Pro	FM001047	Suprasorb Liquacel Pro 160 4x10cm
Suprasorb Liquacel Pro	FM001048	Suprasorb Liquacel Pro 160 4x20cm
Suprasorb Liquacel Pro	FM001049	Suprasorb Liquacel Pro 160 4x30cm
Suprasorb Liquacel Pro	FM001050	Suprasorb Liquacel Pro 160 5x5cm
Suprasorb Liquacel Pro	FM001066	Suprasorb Liquacel Pro 160 5x5cm
Suprasorb Liquacel Pro	FM001020	Suprasorb Liquacel Pro 200 10x10cm
Suprasorb Liquacel Pro	FM001051	Suprasorb Liquacel Pro 200 10x12.5cm
Suprasorb Liquacel Pro	FM001052	Suprasorb Liquacel Pro 200 10x12cm
Suprasorb Liquacel Pro	FM001053	Suprasorb Liquacel Pro 200 10x20cm
Suprasorb Liquacel Pro	FM001054	Suprasorb Liquacel Pro 200 15x15cm
Suprasorb Liquacel Pro	FM001055	Suprasorb Liquacel Pro 200 15x20cm
Suprasorb Liquacel Pro	FM001056	Suprasorb Liquacel Pro 200 1x30cm
Suprasorb Liquacel Pro	FM001057	Suprasorb Liquacel Pro 200 1x45cm
Suprasorb Liquacel Pro	FM001058	Suprasorb Liquacel Pro 200 20x20cm
Suprasorb Liquacel Pro	FM001059	Suprasorb Liquacel Pro 200 20x30cm
Suprasorb Liquacel Pro	FM001060	Suprasorb Liquacel Pro 200 2x30cm
Suprasorb Liquacel Pro	FM001061	Suprasorb Liquacel Pro 200 2x45cm
Suprasorb Liquacel Pro	FM001062	Suprasorb Liquacel Pro 200 4x10cm
Suprasorb Liquacel Pro	FM001063	Suprasorb Liquacel Pro 200 4x20cm
Suprasorb Liquacel Pro	FM001064	Suprasorb Liquacel Pro 200 4x30cm
Suprasorb Liquacel Pro	FM001065	Suprasorb Liquacel Pro 200 5x5cm

EC DECLARATION OF CONFORMITY

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, Amd 1:2013 2015, Amd 2:2019
EN ISO 11137-2	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose	2013, 2015
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
EN ISO 10993-5	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	2009
ISO 10993-6	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation	2016
ISO 10993-10	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	2021
EN ISO 10993-11	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity	2018
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, 2009
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	2020
EN ISO 11607-2	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes	2020
EN ISO 11737-1	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products	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	2020
EN ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes	2016 + AC:2018
EN ISO 14971	Medical devices - Application of risk management to medical devices	2019

EC DECLARATION OF CONFORMITY

EN ISO 15223-1	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	2021
BS EN 62366-1	Medical devices — Part 1: Application of usability engineering to medical devices	2015+ A1:2020
EN ISO 13726-1	Test methods for primary wound dressings - Part 1: Aspects of absorbency	2002 + AC:2003
ISO 14644-1	Cleanrooms and associated controlled environments. Classification of air cleanliness	2015
ISO 14644-2	Cleanrooms and associated controlled environments. Specifications for testing and monitoring to prove continued compliance with ISO 14644-1	2015
EN 1041	Information supplied by the manufacturer of medical devices	2008
EN 556-1	Sterilization of medical devices. Requirements for medical devices to be designated "STERILE" Requirements for terminally sterilized medical devices	2001
ASTM F1980-16	Standard Practice for Performance Testing of Shipping Containers and Systems	2016
ASTM D 4169-16	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices	2016