2.5 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
VENAGRADOC-2	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

EC Declaration of Conformity

European Communities Council Directive 93/42/EEC as amended by 2007/47/EC concerning Medical Devices as transposed into European national law by the member states

The undersigned declares that the products described in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Suprasorb Liquacel Ag
Legal Manufacturer:	Specialty Fibres and Materials Ltd Galaxy House – 31 Herald Way, Binley Industrial Estate, CV3 2RQ, Coventry United Kingdom
Variants:	As per Appendix I – Product Listing/Schedule
Intended Use:	Venus Ag antimicrobial wound dressings can be used for the management of moderately to heavily exuding wounds.
MDD Classification:	Class III – Rule 13
Applicable Standards:	As per Appendix II
GMDN Code:	47045 – Cavity-wound management dressing, antimicrobial
Notified Body:	Kiwa Belgelendirme Hizmetleri A.Ş. (CE1984) Tepeören Mevkii Ankara Asfaltı Maret Arkası ITOSB 9. Cadde No: 15 Tuzla, Istanbul Turkey
CE Certificate Reference:	1984-MDD-21-769
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.
MDD Conformity Assessment Route:	EC Declaration of Conformity in accordance with Annex II of the Medical Device Directive

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

Signature:

Date and Place: 14th September 2021, Coventry

Name: Nyerngoor Korda Hewitt

Position: Director of Regulatory Affairs and Quality

EC DECLARATION OF CONFORMITY

ANNEX I – List of Products

	Product Code	Dimensions	Weight (gsm)	Class
Suprasorb Liquacel Ag	FV000241	5 x 5 cm	120	III
	FV000242	10 x 10 cm	120	III
	FV000243	10 x 12.5 cm	120	III
	FV000244	15 x 15 cm	120	III
	FV000245	2 x 45 cm	120	III
	FV000246 142503	5 x 5 cm	160	III
	FV000247 142504	10 x 10 cm	160	III
	FV000248	10 x 12.5 cm	160	III
	FV000249 142505	15 x 15 cm	160	III
	FV000250 142506	2 x 45 cm	160	III
	FV000251	5 x 5 cm	200	III
	FV000252	10 x 10 cm	200	III
	FV000253	10 x 12.5 cm	200	III
	FV000254	15 x 15 cm	200	III
	FV000255	2 x 45 cm	200	III

Appendix II – Applicable 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
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

EN ISO 13726-1	Test methods for primary wound dressings - Part 1: Aspects of absorbency	2002 + AC:2003
EN ISO 14155	Clinical investigation of medical devices for human subjects - Good clinical practice	2011
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 E2149-13a	Standard Test Method for Determining the Antimicrobial Activity of Antimicrobial Agents Under Dynamic Contact Conditions	2013
ASTM D 4169-16	Standard Practice for Performance Testing of Shipping Containers and Systems	2016
AATCC 100	TM100-TM 100 Antibacterial Finishes on Textile Materials	2012
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 of usability 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