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
VENAGRADOC-20	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

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 for SFM. MT-AR-000000234 for Advena.
Intended Use:	Askina® Calgitrol® Ag+ antimicrobial wound dressings can be used for the management of moderately to heavily exuding wounds.
General Product Name/s:	Askina® Calgitrol® Ag+
Variants:	As per Annex I – Product Listing
Applicable Standards:	As Per Annex II
Classification:	Class III – Rule 13
GMDN Code/Term:	47045
Basic UDI-DI:	N/A
Conformity Assessment Procedure:	EC Declaration of Conformity in accordance with Annex II of the Medical Device Directive certificate number 1984-MDD-21-752 SFM Annex II.3
Notified Body:	Kiwa Belgelendirme Hizmetleri A.Ş. (CE1984) Tepeören Mevkii Ankara Asfaltı Maret Arkası ITOSB 9. Cadde No: 15 Tuzla, Istanbul Turkey
Authorised Representative:	Advena Ltd Tower Business Centre, 2nd Floor, Tower Street, Swatar, BKR 4013 Malta
EC Certificate Number:	1984-MDD-21-769
Expiry Date	27 May 2024

Signature: 

Date and Place: 20th June 2023, Coventry

Name: Nyerngoor Korda Hewitt

Position: Director of RAQ

EC DECLARATION OF CONFORMITY

ANNEX I – Product Listing

Sage Product Codes	Product Models (Commercial Names(Brands))	Product Variants (Commercial Name/Dimensions)
FV000271	Askina® Calgitrol® Ag+	Askina® Calgitrol® Ag+ 120 10x10cm
FV000272	Askina® Calgitrol® Ag+	Askina® Calgitrol® Ag+ 120 10x12.5cm
FV000276	Askina® Calgitrol® Ag+	Askina® Calgitrol® Ag+ 120 10x12cm
FV000283	Askina® Calgitrol® Ag+	Askina® Calgitrol® Ag+ 120 10x20cm
FV000284	Askina® Calgitrol® Ag+	Askina® Calgitrol® Ag+ 120 15x20cm
FV000281	Askina® Calgitrol® Ag+	Askina® Calgitrol® Ag+ 120 1x30cm
FV000282	Askina® Calgitrol® Ag+	Askina® Calgitrol® Ag+ 120 1x45cm
FV000285	Askina® Calgitrol® Ag+	Askina® Calgitrol® Ag+ 120 20x20cm
FV000280	Askina® Calgitrol® Ag+	Askina® Calgitrol® Ag+ 120 2x30cm
FV000277	Askina® Calgitrol® Ag+	Askina® Calgitrol® Ag+ 120 4x10cm
FV000278	Askina® Calgitrol® Ag+	Askina® Calgitrol® Ag+ 120 4x20cm
FV000279	Askina® Calgitrol® Ag+	Askina® Calgitrol® Ag+ 120 4x30cm
FV000270	Askina® Calgitrol® Ag+	Askina® Calgitrol® Ag+ 120 5x5cm
FV000273	Askina® Calgitrol® Ag+	Askina® Calgitrol® Ag+ 15x15cm
FV000287	Askina® Calgitrol® Ag+	Askina® Calgitrol® Ag+ 160 10x10cm
FV000288	Askina® Calgitrol® Ag+	Askina® Calgitrol® Ag+ 160 10x12.5cm
FV000292	Askina® Calgitrol® Ag+	Askina® Calgitrol® Ag+ 160 10x12cm
FV000299	Askina® Calgitrol® Ag+	Askina® Calgitrol® Ag+ 160 10x20cm
FV000289	Askina® Calgitrol® Ag+	Askina® Calgitrol® Ag+ 160 15x15cm
FV000300	Askina® Calgitrol® Ag+	Askina® Calgitrol® Ag+ 160 15x20cm
FV000297	Askina® Calgitrol® Ag+	Askina® Calgitrol® Ag+ 160 1x30cm
FV000298	Askina® Calgitrol® Ag+	Askina® Calgitrol® Ag+ 160 1x45cm
FV000301	Askina® Calgitrol® Ag+	Askina® Calgitrol® Ag+ 160 20x20cm
FV000291	Askina® Calgitrol® Ag+	Askina® Calgitrol® Ag+ 160 20x30cm
FV000296	Askina® Calgitrol® Ag+	Askina® Calgitrol® Ag+ 160 2x30cm
FV000290	Askina® Calgitrol® Ag+	Askina® Calgitrol® Ag+ 160 2x45cm
FV000293	Askina® Calgitrol® Ag+	Askina® Calgitrol® Ag+ 160 4x10cm
FV000294	Askina® Calgitrol® Ag+	Askina® Calgitrol® Ag+ 160 4x20cm
FV000295	Askina® Calgitrol® Ag+	Askina® Calgitrol® Ag+ 160 4x30cm
FV000286	Askina® Calgitrol® Ag+	Askina® Calgitrol® Ag+ 160 5x5cm
FV000303	Askina® Calgitrol® Ag+	Askina® Calgitrol® Ag+ 200 10x10cm
FV000304	Askina® Calgitrol® Ag+	Askina® Calgitrol® Ag+ 200 10x12.5cm
FV000308	Askina® Calgitrol® Ag+	Askina® Calgitrol® Ag+ 200 10x12cm
FV000315	Askina® Calgitrol® Ag+	Askina® Calgitrol® Ag+ 200 10x20cm
FV000305	Askina® Calgitrol® Ag+	Askina® Calgitrol® Ag+ 200 15x15cm
FV000316	Askina® Calgitrol® Ag+	Askina® Calgitrol® Ag+ 200 15x20cm
FV000313	Askina® Calgitrol® Ag+	Askina® Calgitrol® Ag+ 200 1x30cm
FV000314	Askina® Calgitrol® Ag+	Askina® Calgitrol® Ag+ 200 1x45cm

EC DECLARATION OF CONFORMITY

FV000317	Askina® Calgitrol® Ag+	Askina® Calgitrol® Ag+ 200 20x20cm
FV000307	Askina® Calgitrol® Ag+	Askina® Calgitrol® Ag+ 200 20x30cm
FV000312	Askina® Calgitrol® Ag+	Askina® Calgitrol® Ag+ 200 2x30cm
FV000306	Askina® Calgitrol® Ag+	Askina® Calgitrol® Ag+ 200 2x45cm
FV000309	Askina® Calgitrol® Ag+	Askina® Calgitrol® Ag+ 200 4x10cm
FV000310	Askina® Calgitrol® Ag+	Askina® Calgitrol® Ag+ 200 4x20cm
FV000311	Askina® Calgitrol® Ag+	Askina® Calgitrol® Ag+ 200 4x30cm
FV000302	Askina® Calgitrol® Ag+	Askina® Calgitrol® Ag+ 200 5x5cm
FV000275	Askina® Calgitrol® Ag+	Askina® Calgitrol® Ag+ 20x30cm
FV000274	Askina® Calgitrol® Ag+	Askina® Calgitrol® Ag+ 2x45cm

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	2015/A2:2019
EN ISO 11137-2	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose	2015+A1:2023
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	2020
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	2023
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	2021
EN ISO 10993-17	Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances	2009
EN ISO 10993-18	Biological evaluation of medical devices - Part 18: Chemical characterization of materials	2020
EN ISO 11607-1	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems	2020

EC DECLARATION OF CONFORMITY

EN ISO 11607-2	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes	2020/A11:2022
EN ISO 11737-1	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products	2018 / A1:2021
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
EN ISO 14155	Clinical investigation of medical devices for human subjects - Good clinical practice	2020
EN 13726-1	Test methods for primary wound dressings - Part 1: Aspects of absorbency	2023
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 4169-22	Standard Practice for Performance Testing of Shipping Containers and Systems	2022
ASTM F1980-16	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices	2021
EN 556-1	Sterilization of medical devices. Requirements for medical devices to be designated "STERILE" Requirements for terminally sterilized medical devices	2001 / AC:2006
EN ISO 20417	Medical devices - Information to be Supplied by the Manufacturer	2021
EN 62366-1	Medical devices — Part 1: Application of usability engineering to medical devices	2015

EC DECLARATION OF CONFORMITY

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