

DECLARATION OF IDENTICAL BUILT

Date: 01/12/2023

To Whom it may concern,

We, Speciality Fibres and Materials Ltd., Galaxy House 31 Herald Way, Binley Industrial Estate, CV3 2RQ, Coventry, United Kingdom hereby declare that the product “Venus Ag” is the same product as Askina® Calgitrol® Ag+. The name Venus Ag is the project name and Askina® Calgitrol® Ag+ is the commercial name of Venus Ag for marketing purposes only.

Consequently, the following technical documents that refer to the product Venus Ag are applicable to Askina® Calgitrol® Ag+:

- *Product specifications*
- *Instructions for Use*
- *Manufacturing process description*
- *List of Standards*
- *Essential Requirements or Essential Principles or General Safety and Performance Requirements report*
- *Product design and development files*
- *Shelf life/Stability Studies*
- *Sterilisation validation report*
- *Preclinical data such as biological, biocompatibility and toxicological evaluations*
- *Clinical Evaluation Report*
- *Post- market surveillance data*
- *Certificate of analysis (CoA)*
- *Design validation & verification*
- *Technical/engineering drawings*
- *Tests reports showing compliance with specific standards*
- *Physical and mechanical characterization*
- *Material/chemistry characterization*
- *Usability testing and human factors*

Speciality Fibres and Materials Ltd

Name, Position: Nyerngoor Korda Hewitt
Director of Regulatory Affairs and Quality

Signature, Stamp:


