



profümed GmbH • Wechselbundesstraße 81 • 2840 Grimmenstein • Austria







## Produkte für Medizin

Unser Zeichen: Datum:

BG / pr 23-Mar-21

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**EG- Declaration of conformity for medical devices** 

We herewith declare,

that the product mentioned below, which is manufactured by Profümed GmbH, Wechselbundesstraße 81 in 2840 Grimmenstein under sole responsibility of Profümed GmbH, complies with the relevant provisions, in particular the Essential Requirements of the following regulation

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices

The required conformity assessment procedure according to Attachment IX has been carried out, confirmed by the certification body of TÜV Süd Product Service Ltd, the standards according to STED (Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices) have been met and the technical documentation is available.

Product: SURGICAL CELLULOSE in layers and in rolls

Product description	REF:	Basic UDI-DI:
Askina®Cel 1x15 kg highly bleached	9050035	4022495243362
Askina®Cel 1x15 kg unbleached	9050523	4022495243416
Askina®Cel 1x100 g roll highly bleached	9050418	4022495243317

Classification according to MDR 2017/745 Attachment VIII:

Class I

Grimmenstein,

23.03.2021

Managing Director Profümed GmbH

Herbert Baumgartner

Effective

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