

Declaration of Conformity

We

Winner Medical Co., Ltd.
Winner Industrial Park, No. 660 Bulong Road, Longhua District, 518109 Shenzhen, China

Manufacturer according to Medical Device Regulation (EU) 2017/745

hereby declare in our own responsibility
that the products

Askina® Verbandmull

Gauze dressing without X-ray detectable element are wound treatment device and primarily intended to be used as mechanical barrier, for compression or for absorption of exudates.

Among them, gauze trach sponge has special shape intended to be used in tracheotomy nursing process for absorbing exudates and skin, wound care. This is a single use device and should be in sterile state before use.

Basic UDI-DI: 694109403798FU
(article numbers see attachment I)

are in conformity with the requirements of the Medical Device Regulation (EU) 2017/745

Conformity Assessment Procedure

according to article 52 section 7
of the Regulation named above

Classification

according to annex VIII of the Regulation named above
Class I

Authorized Representative for the European Union (Article 11)

Shanghai International
Holding Corp. GmbH (Europe)
Eiffenstraße 8
20537 Hamburg
Germany

Attachment I

Art. No.	Product name	Class
9030050W	Askina® Verbandmull	I
9030409W	Askina® Verbandmull	I
9030107W	Askina® Verbandmull	I
9030026W	Askina® Verbandmull	I

Signature:

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Date: 2021.05.10

Name and Position: Jing Xu --Registration and Quality System Manager

Company Stamp/Seal

Winner Medical Co., Ltd.

