Effective

Declaration of Conformity

We

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

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

hereby declare in our own responsibility
that the products

Askina® Pore
Askina® Silk
Askina® Film

Askina® Pore: Latex-free, surgical paper tape. It is breathable and gentle to skin yet adheres well and leaves minimal adhesive residue upon removal.
Askina® Silk: Latex-free, surgical tape. It is breathable and gentle to the skin and offers high strength and good initial adhesion.
Askina® Film: Latex-free and gentle to the skin, yet adheres very well without leaving any residue upon removal.

Basic UDI-DI:

Askina® Pore:	694109403887FU
Askina® Silk:	694109403888FW
Askina® Film:	694109403884FN

(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

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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
9080015N	Askina® Silk	I
9080023N	Askina® Silk	I
9080112N	Askina® Silk	I
9080120N	Askina® Silk	I
9080228N	Askina® Silk	I
9081020N	Askina® Pore	I
9081500N	Askina® Film	I
9081518N	Askina® Film	I

Signature: 徐静
Date: 2021.05.11
Name and Position: Jing Xu --Registration and Quality System Manager
Company Stamp/Seal
Winner Medical Co., Ltd.

WINNER MEDICAL CO., LTD. 稳健医疗用品股份有限公司 质量部

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