The Declaration of Conformity

Manufacturer: Huizhou Foryou Medical Devices Co., Ltd.

Add. North Shangxia Rd., Dongjiang Hi-tech Industry Park,

516005, HuiZhou, P. R. China.

<u>European</u>

Representative: Shanghai International Holding Corp.GmbH(Europe)

<u>Add.</u> Eiffestrasse 80, 20537 Hamburg, Germany

<u>Products Name:</u> Super Absorbent Dressing

Size Specification: Listed in Annex I

GMDN Code: P46854

Classification: II b, MDD 93/42/EEC Appendix IX, Rule4

Conformity Assessment Route: Annex II.3 of MDD 93/42/EEC

<u>Distributor:</u> Lohmann & Rauscher International GmbH & Co KG,

Westerwaldstraße 4, 56579 Rengsdorf, Germany

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

The manufacturer is exclusively responsible for the declaration of conformity.

Directives

General Applicable Directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC concerning medical devices (MDD 93/42/EEC).

Standards Applied: All applicable standards.

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstr. 65,

D-80339 München, Germany

Identification Number: CE0123

(EC)Certificate(s): G1 065520 0034 Rev. 02

Expire Date of the Certificate: 2023-07-24 **Start CE Marking:** 2016-12-20

Place and Date of Issue: Huizhou / 2020-10-13

Signature:

Name: Zhang Yang

Position: Management Representative

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Annex I

This appendix declares the products included in the above Referenced Declaration of Conformity.

Product	LR REF	Product size (cm)	Foryou REF
Vliwasorb sensitive	141820	7.5X7.5 (5x5) CM	SP075075AF
	141821	12.5X12.5 (10x10) CM	SP125125AF
	141822	10X20 (7.5x17) CM	SP200100AF
	141823	15X25 (12x22) CM	SP250150AF
	141824	20X20 (17x17) CM	SP200200AF
	141825	20X30 (17x27) CM	SP300200AF
	141828	12.5X12.5 (10x10) CM	SP125125AF
	141829	10X20 (7.5x17) CM	SP200100AF
	141830	15X25 (12x22) CM	SP250150AF
	141831	20X20 (17x17) CM	SP200200AF
	141832	20X30 (17x27) CM	SP300200AF

Signature:

Name: Zhang Yang

Position: Management Representative