Lohmann & Rauscher

KONFORMITÄTSERKLÄRUNG/ ***Declaration of Conformity***	**KFE 0011-04**

Wir/*We* Lohmann & Rauscher International GmbH & Co. KG

Westerwaldstraße 4, D-56579 Rengsdorf

erklären in alleiniger Verantwortung, dass das Produkt (die Produktgruppe)/
declare on our own responsibility that the product (group of products)

Gazin® Tamponadebinde
Ribbon Gauze
(Bezeichnung/*Name*)

REF 13470, 13471, 13473

GMDN-Code	36226 *Verband, Wundhöhlenversorgung/* *cavity-wound management dressing*

den einschlägigen Anforderungen der Richtlinie 93/42/EWG entspricht/
meets all the requirements of the Directive 93/42/EEC which apply to him

Angewandte harmonisierte Produktnormen: *Applied harmonized product standards:*	s. Liste der Standards *s. list of standards*
Konformitätsbewertungsverfahren/ *Conformity Assessment procedure*	Anhang II.3 *Annex II.3*
Klassifizierung, Regel/ *Classification, Rule*	IIa, R.7
Benannte Stelle (falls zutreffend)/ *Notified Body (if applicable)*	TÜV SÜD Product Service GmbH (CE0123) Ridlerstr. *65* D-80339 München
Datum der ersten CE-Kennzeichnung)/ *Date of the first CE-Labelling*	11.02.2008

Neuwied, am 07.04.2011
Ort, Datum /*place, date*

Eva Rudel
Stellv. QM-Beauftragter der Geschäftsführung/
Dep. Quality Management Representative

Anlage 1/Annex 1 zu QMV 04-003
Stand: 2010-05-25

Datenblatt

Declaration of Conformity

Dokumentennummer:	KFE_0011
Versionsnummer:	1.0
Lifecycle-Status:	350 Effective (geltend)
Gültig ab:	07.04.2011
Gültig bis:	Unbegrenzt gültig
Autor:	

People.Health.Care.

EU DECLARATION OF CONFORMITY

DOC 0103-01

(EN)

We hereby declare under our sole responsibility, that the following products comply with the following legislations:

Manufacturer	**Lohmann & Rauscher International GmbH & Co. KG** Westerwaldstraße 4 56579 Rengsdorf Germany
SRN	DE-MF-000005052
Applicable legislations	Regulation (EU) 2017/745 on medical devices
Product group	**Triangular Cloth**
Catalog Numbers	DI_REF_00160_02
Basic UDI-DI	4021447-0103-K2
Class / Rule	I / 01
Conformity assessment route:	Technical Documentation acc. to Annex II + III

Neuwied — 15.09.22

Place, Date

Lohmann & Rauscher International GmbH & Co. KG

Oliver Opitz, Management Representative

Datenblatt

Declaration of Conformity

Dokumentennummer:	DOC-0103
Versionsnummer:	2.0
Lifecycle-Status:	350 Effective (geltend)
Gültig ab:	
Gültig bis:	
Autor:	Limbach, Christian (ChristianL)

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 002037 0010 Rev. 01

Manufacturer

Allmed Medical Products Co., Ltd
No.18 Qixing Road, Majiadian Town
443200 Zhijiang City, Hubei Province
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, GERMANY

Product Category(ies):

**Gauze Swabs, Non Woven Swabs,
Drain Sponges, Post-Op Sponges,
ABD Pads, Fluffy Gauze Bandages,
Fluffy Gauze Swabs,
Cotton-Filled Exodontia Sponges,
Gauze, Medical kits,
Gauze Balls, Non-woven Balls,
Non Stick Pads, Eye Pads,
Triangular Bandages, Adhesive Bandage,
Elastic Bandages, Adhesive dressing,
Tongue Depressors and Cotton Applicators**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: SH19256EXT01

Valid from: 2019-09-09
Valid until: 2024-05-26

Date, 2019-06-21

Stefan Preiß
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 002037 0010 Rev. 01

Facility(ies):

Allmed Medical Products Co., Ltd
No.18 Qixing Road, Majiadian Town, 443200
Zhijiang City, Hubei Province, PEOPLE'S
REPUBLIC OF CHINA

Allmed Medical Products Co., Ltd.
No. 180 Gong Yuan Road, Majiadian Town, 443200
Zhijiang City, Hubei Province, PEOPLE'S
REPUBLIC OF CHINA

Allmed Medical Products Co., Ltd.
No. 76, You Yi Road, Majiadian Town, 443200
Zhijiang City, Hubei Province, PEOPLE'S
REPUBLIC OF CHINA

Allmed Medical Products Co., Ltd.
No. 99, Jin Shan Road, Majiadian Town, 443200
Zhijiang City, Hubei Province, PEOPLE'S
REPUBLIC OF CHINA

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
TÜV SÜD

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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TÜV®

A4 / 07.17

No.18 Qixing Road, Majiadian Town, 443200 Zhijiang City,
Hubei Province, P.R.C
Tel: 86 717 4211111 Fax: 86 717 4225499

ALLMED

WI-CE-A

Declaration of Conformity

Manufacturer: Allmed Medical Product s Co.,Ltd

Address: No.18 Qixing Road, Majiadian Town, 443200 Zhijiang City, Hubei province, PEOPLE'S REPUBLIC OF CHINA

European Representative: Shanghai International Holding Corp. GmbH(Europe)

Address: Eiffestrasse 80, 20537 Hamburg, Germany

Product Name: Eye Pads
UMDNS Code: 11661
Model Number: 142020，142023，142024，142025
Classification (MDD, Annex IX):I sterile
Classification Rule:4
Conformity Assessment Route: MDD93/42/EEC Annex V.

We herewith declare in our own responsibility 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. We are exclusively responsible for the declaration of conformity.

DIRECTIVES

Medical Device Directive: The object of the declaration described above is in conformity with the Council Directive MDD 93/42/EEC.

Standard Applied: All applicable harmonised standard (published in the official journal of the European Communities).

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstrasse 65, 80339 MÜnchen, Germany
Identification number: 0123
(EC) Certificate(s): G2S 002037 0010 Rev.02
Expire date of the Certificate: 2024-05-26
Start of CE Marking: not start
Place, Date of Issue: Hubei, 2020-09-01

Signature: Vince Tian Mar. 18. 2020 General Manager of Quality

Name: Vince Tian Position: