

EU Certificate

Production Quality Assurance

REGULATION (EU) 2017/745 on Medical Devices, Annex XI, Part A



Registration No.: DZ 2372869-1

Manufacturer: **Fomed Industries Inc.**
20 Han Sha Road, Hou Hu District,
Qianjiang City,
433115 Hubei
P.R. China

EUDAMED Single
Registration No.: CN-MF-000012944

Products: Products of class IIa:
M020103-LAPAROTOMY COTTON GAUZES
M020102-COTTON GAUZES, FOLDED

Products of class I, sterile:
M020102-COTTON GAUZES, FOLDED
M020201-NON-WOVEN FOLDED GAUZES
M040201-ABSORBENT DRESSINGS WITH CELLULOSE PAD AND NON-
WOVEN WRAPS

The scope of certification is limited to the aspects relating to establishing, securing
and maintaining sterile conditions

Authorised
representative(s): Shanghai International Holding Corp. GmbH(Europe)
Eiffestrasse 80, 20537 Hamburg, Germany

Certificate history		
Revision:	Description:	Issue date:
0	Initial Revision	2023-07-17

The Notified Body hereby declares that the requirements of Annex XI, Part A of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a production quality assurance, which is subject to periodic surveillance, defined by Annex XI, Part A, Section 7 of the aforementioned regulation. If class III devices or class IIb devices are covered by this certificate, an EU type-examination certificate in accordance with Annex X of the aforementioned regulation is required before placing them on the market.

Report No.: 10920867-120

Effective date: 2023-07-17

Expiry date: 2028-07-16

Issue date: 2023-07-17



Fuxiu Sheng
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.

TÜV Rheinland LGA Products GmbH • 51105 Köln

Fomed Industries Inc.

20 Han Sha Road, Hou Hu District,
Qianjiang City,
433115 Hubei
P.R. China

Contact

Tel. +49 911 655-5225

Mail: medical-products@de.tuv.com

Date July 18, 2023

Application for: QMS

Certificate No. : DZ 2372869-1

Requirement : REGULATION (EU) 2017/745 on Medical Devices, Annex XI, Part A

Dear Madame or Sir,

Your Quality Management System has been audited and fulfills the above-mentioned requirement.

Enclosed please find the certificate No. DZ 2372869-1.

Best regards,



Fuxiu Sheng
Certification body

TÜV Rheinland
LGA Products GmbH

Am Grauen Stein
51105 Köln
Germany

Headquarter

Tillystraße 2
90431 Nuremberg

Phone. +49 911 655 5225.
Fax +49 911 655 5226
service@de.tuv.com
www.tuv.com/safety

Board of Management

Dipl.-Ing.
Jörg Mähler, Spokesman

Dipl.-Kfm.
Dr. Jörg Schlösser

Nuremberg HRB 26013
VAT No.: DE 811835490

Chairman of the
Supervisory Board

Dr. Michael Föbi