EU Certificate

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

TÜVRheinland®

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.

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Issue date:	2023-07-17

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-091

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

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