

CE EC Declaration of Conformity
Regarding Medical Device Regulation (EU)2017/745

Manufacturer: FOMED INDUSTRIES INC.

Address: 20 Han sha Road, Houhu District, 433115 Qianjiang City, Hubei Province,
PEOPLE'S REPUBLIC OF CHINA.

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

Address: Eiffestrasse 80, 20537 Hamburg!Germany

Product Name: Self Sealing Sterilization Pouch,Bowie Dick Test,Autoclave Integrators
Card,Dental Cotton Roll,Non-woven Swabs,Dental Bibs,Impression Tray,Isolation
Gown,Steam Sterilization Indicator Tape,Mob cap,Dental Barrier Film,CPE Shoe
Cover,Dental Chair Covers.

Model: Customized.

Specification: Can be customized.

Classification: Class I

Rule: According to Rule 1, Annex VIII, Chapter III of Medical Device Regulation
(EU)2017/745

Conformity assessment procedure: Annex II+III

Basic UDI-DI:

697368504ZFDLN016W,697368504BDCSYN01B4,697368504ZSKXN01H8,
697368504YKMJGN01RH,697368504WFBPEN01JT,697368504YKDVN01AL,697368
504YTYN025R,697368504GLYJN0162,697368504SJDYN01WS,697368504HSMVN01
7W,697368504WFBPES01KL,697368504YTYN025R,697368504YYTYN01NF.

SRN: CN-MF-000012944

We confirm our product can meet the requirement of Medical Device Regulation and
the following harmonized standards:

EN ISO 14971: 2019, EN 1041: 2008+AI:2013, EN ISO 15223-1: 2016, ISO 10993-1:
2018, EN ISO 10993-5: 2009, EN ISO 10993-10: 2013, EN ISO 11607-1/2:2017, EN
ISO 11140-1:2014, ASTM F: 1980-2.

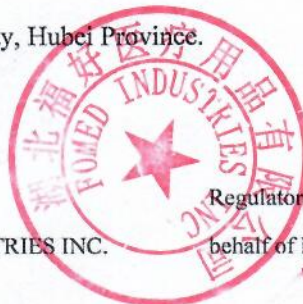
Place, Date of

Issue: Qianjiang City, Hubei Province.
2025.4.10

Signature: Alain PAN

General Manager

For and on behalf of FOMED INDUSTRIES INC.



Regulatory Affairs Supervisor For and on
behalf of FOMED INDUSTRIES INC.