

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: Dental Cotton Rolls,Sterilization Pouches,Non-woven Swabs,Dental
Barrier Film,Dental Bibs,Cotton Rolls Dispencer,CPE Shoe Cover,Impression
Tray,Surgical Gloves,Dental Examination Kits.

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

UDI:697368504ZFDLN016W,697368504YKMJGNN01RH,697368504SBPWXCS01F
H,697368504SBPWXCN01EQ,697368504WFBPEN01JT

SRN: CN-MF-00001294

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.

Signature: Alain PAN



General Manager

For and on behalf of FOMED
INDUSTRIES INC.

Regulatory Affairs Supervisor

For and on behalf of FOMED
INDUSTRIES INC.