



BenQ Materials Corp.

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EC Declaration of Conformity

For the following equipment :

Bleeding Management Device – Sterile Wound Dressing

(Product Name)

Chito-SAM100: CG series

(Model, Designation)

Old Part Number	New Part Number	Description
CTS101-44	CT101-A-EN	4''x 4'' (10cm x 10cm), 3''x 4' (7.6 cm x 1.22m) 3''x 6' (7.6 cm x 1.83m)
CTS101-04	CT101-B-EN	4''x 4'' (10cm x 10cm), 3''x 4' (7.6 cm x 1.22m) 3''x 6' (7.6 cm x 1.83m)
CTS101-06	CT101-EN	4''x 4'' (10cm x 10cm), 3''x 4' (7.6 cm x 1.22m) 3''x 6' (7.6 cm x 1.83m)

is herewith confirmed to comply with the requirements set out in the Council Directive on the harmonization of the Laws of the Member States concerning Medical Device Directive 93/42/EEC As Amended by 2007/47/EC with the compliance the essential requirement – Annex I and the conformity assessment to article 11.1a and Annex II to be certified by DNV GL Presafe AS (Notify Body number – 2460).

For the evaluation regarding the Class III (by Rule 17, Annex IX) product safety aspects, the referenced harmonized standards are applied.

The following European Authorized Representative is stated to the declaration :

MedNet GmbH

Borkstrasse 10, 48163 Muenster, Germany

Tel: +49 251 32266 62/Email: Info@medneteuropa.com

(Company Name / Address)

The following person is exclusively responsible for the compliance of declaration :

BenQ Materials Corporation

29, Jianguo E. Road, Gueishan, Taoyuan, 33341, Taiwan, R.O.C.

(Manufacturer Name/Address)

ZC Chen

CEO & Chairman of BenQ Materials Corporation

(Name / Position)

(Legal Signature)

2019/08/01

(Date)