BenQ Materials Corp.

29, Jianguo E. Rd., Gueishan,
Taoyuan, Taiwan, R.O.C.
Tel: +886-3-374-8880
Fax:+886-3-374-8888
BenQMaterials.com

EC Declaration of Conformity

For the following equipment :

Bleeding Management Device – Sterile Wound Dressing
AnsCare ChitoClot Gauze: CG series, CX series
ChitoSAM™100
(Product Name)

AnsCare ChitoClot Gauze: CG-212-1, CG-212-2, CG-212-3, CG-212-4, CG-212-5, CG-212-6, CG-212-7, CG-212-8, CG-212-9, CG-212-A, CG-212-B, CX-210-A, CX-210-B, CX-210-C, CX-210-D, CX-210-E
ChitoSAM™100: CT101-B-EN, CT101-A-EN, CT101-C-EN, CS101-10
(Model, Designation)

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 Product Assurance AS**, located at Veritasveien 3, 1363 Høvik, Norway (Notify Body number – 2460).

For the evaluation regarding the Class III product safety aspects, the referenced harmonized standards are applied.

The following European Authorized Representative is stated to the declaration :

Obelis S.A
Bd. Général Wahis 53, 1030 Brussels, Belgium
Tel: +32 2 732 59 54 /Email: mail@obelis.net
(Company Name / Address)

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

BenQ Materials Corporation
29, Jianguo E. Road, Gueishan, Taoyuan, Taiwan
(Manufacturer Name/Address)

ZC Chen
CEO & Chairman of BenQ Materials Corporation
(Name / Position)

(Legal Signature)

2021/03/26
(Date)

BenQ Materials Corp.

29, Jianguo E. Rd., Gueishan,
Taoyuan, Taiwan, R.O.C.
Tel: +886-3-374-8880
Fax:+886-3-374-8888
BenQMaterials.com

Harmonized Standard

The following harmonized standard is applied to the essential requirement.
The all content shall be updated, according to the 93/42/EEC (2007/47/EC)

- **EN 1041:2008** Information supplied by the manufacturer of medical devices
- **EN 13726-1:2002** Test methods for primary wound dressings-Part 1: Aspects of absorbency
- **EN ISO 10993-1:2018** Biological evaluation of medical devices-Part 1: Evaluation and testing within a risk management process
- **EN ISO 10993-5: 2009** Biological evaluation of medical devices-Part 5: Test for in vitro cytotoxicity
- **EN ISO 10993-10:2010** Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization
- **EN ISO 10993-11:2018** Biological evaluation of medical devices Part 11: Tests for systemic toxicity
- **EN ISO 11137-1:2015** Sterilization of health care products-Radiation-Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
- **EN ISO11137-2:2015** Sterilization of health care products-Radiation –Part 2: Establishing the sterilization dose
- **EN ISO 11607-1:2009** Packaging for Terminally Sterilized Medical Devices-Part 1 : Requirements for materials, sterile barrier systems and packaging systems
- **EN ISO 11607-2:2006** Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes
- **EN ISO 11737-1:2006** Sterilization of medical devices-Microbiological methods-Part 1: Determination of a population of microorganisms on products
- **EN ISO 11737-2:2009** Sterilization of medical devices –Microbiological methods-Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
- **EN ISO 13485:2016** Medical devices- Quality management systems-Requirements for regulatory Purposes
- **EN ISO 14155:2011** Clinical investigation of medical devices for human subjects — Good clinical practice
- **EN ISO 14971:2012** Medical devices-Application of risk management to medical devices

BenQ Materials Corp.

29, Jianguo E. Rd., Gueishan,
Taoyuan, Taiwan, R.O.C.
Tel: +886-3-374-8880
Fax:+886-3-374-8888
BenQMaterials.com

- **EN ISO 15223-1:2016** Medical devices-Symbols to be used with medical device labels, labelling and information to be supplied-Part 1: General requirements
- **EN ISO 22442-1:2015** Medical devices utilizing animal tissues and their derivatives -- Part 1: Application of risk management
- **EN ISO 22442-2: 2015** Medical devices utilizing animal tissues and their derivatives – Part 2: Controls on sourcing, collection and handling.
- **EN ISO 22442-3:2007** Medical devices utilizing animal tissues and their derivatives -- Part 3: Validation of the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents

BenQ Materials Corp.

29, Jianguo E. Rd., Gueishan,
Taoyuan, Taiwan, R.O.C.
Tel: +886-3-374-8880
Fax:+886-3-374-8888
BenQMaterials.com

Non-Harmonized Standard

- **ASTM F88-15** Standard Test Method for Seal Strength of Flexible Barrier Materials
- **ASTM F756-17** Standard Practice for Assessment of Hemolytic Properties of Materials
- **ASTM F1929-15** Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- **ASTM F1980-16** Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- **IEC 62366-1:2015** Medical devices - Application of usability engineering to medical device
- **IEC 62366-2:2016** Medical devices — Part 2: Guidance on the application of usability engineering to medical devices
- **ISO 9073-18:2007** Textiles-Test methods for nonwovens—Part 18: Determination of breaking Strength and elongation of nonwoven materials using the grab tensile test
- **ISO 10993-2:2006** Biological evaluation of medical devices Part 2: Animal welfare requirements
- **ISO 10993-12:2012** Biological evaluation of medical devices Part 12: Sample preparation and reference materials
- **ISO 10993-18:2020** Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process
- **ISO 14644-1:2015** Cleanrooms and associated controlled environments
- **ISTA 3A:2018** Packaged-Product Test
- **MEDDEV 2.7/1 rev. 4** Clinical evaluation: Guide for manufacturers and notified bodies
- **MEDDEV 2.12/1 rev.8** Market surveillance
- **USP <151>** Pyrogenicity Test (the rabbit pyrogen test)
- **USP <467>** Residual Solvents: Ethanol
- **USP Official Monographs/Chitosan**