BenQ Materials Corp.

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

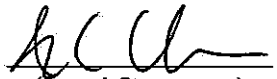
The following European Authorized Representative is stated to the declaration :

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)

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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

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- **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

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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**

BenQ Materials Corporation
29, Jianguo E. Road, Gueishan, Taoyuan, Taiwan, R.O.C.

DNV
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Date:	**Our reference:**	**Your reference:**
2024-04-09	PRJN-194485-2020-PA-TWN	10529-2017-CE-RGC-NA-PS Rev 4.0 10778-2017-CE-RGC-NA-PS Rev 5.0

Confirmation Letter

This letter confirms that, DNV Product Assurance AS, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number NB 2460 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR from

BenQ Materials Corporation

Manufacturer has formally requested DNV for MDR certification and sign a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR

Status:

We, DNV Product Assurance AS, hereby confirm that the required certification is in process. The following activities are included in certification agreement to be covered of the existing MDD_ 93/42/EEC as amended certificate number _ 10529-2017-CE-RGC-NA-PS Rev 4.0/ 10778-2017-CE-RGC-NA-PS Rev 5.0

The transition timelines that apply to the devices covered by the certification agreement, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown as the transition timelines that apply to the devices covered by the agreement subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown as

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth, crowns, screws, wedges, plates, wires, pins, clips, and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

Lin, Dennis
Digitally signed by Lin, Dennis
Date: 2024.04.09 23:17:12 +08'00'

Dennis Lin
DNV Business Assurance Co., Ltd, Product Assurance Director