BenQ Medical Technology Corporation

EU Declaration of Conformity

Manufacturer:	BenQ Medical Technology Corp. Head Office: 7th Floor, No.46, Zhou-z Street, Nei-hu, Taipei 114, Taiwan, and R.O.C. Gueishan Factory:3F, No. 159, Shan-Ying Road, Shan-Ding Village, Gueishan Dist., Taoyuan City 333, Taiwan, R.O.C. SRN Code : TW-MF-000012212
Authorized Representative:	MedNet EC-REP GmbH Borkstrasse 10,48163 Münster, Germany
Medical Device:	Surgical table (Active) GMDN code : 13949, 35393 NOT-5600, Dr. Max 5800, Dr. Max 7000, TriMax 650NS, Poseidon Q100, Poseidon Q200 Series Product detail information see next page.

This declaration of conformity is issued under the sole responsibility of BenQ Medical Technology Corp, is herewith confirmed to comply with the requirements set out in the Regulation (EU) MDR 2017/745, Annex IV (EU Declaration of Conformity), Class I Medical Device(non-sterile, non-measuring function, non-reusable surgical instrument), the classification rule according to Annex VIII of the MDR, Rules 13, and the applicable conformity procedure according to Annex II and III of the MDR.

This declaration is supported by the Quality System approval to ISO 13485 issued by SGS. All supporting documentation is retained at the premises of the manufacturer.

For the evaluation regarding the product safety aspects, the following CS and standards were applied:

EN ISO 13485:2016, ISO 13485:2016, EN ISO 14971:2012, ISO 14971:2019, IEC 60601-1:2005+A1:2012, EN 60601-1:2006+A1:2013, IEC 60601-1-2:2014, EN 60601-1-2:2015, IEC 60601-2-46:2010, EN 60601-2-46:1998, IEC 62304:2006, EN 62304:2006, EN 1041:2008, IEC 62366:2015, EN 62366:2008, EN ISO 15223-1:2016, ISO 15223-1:2016, EN ISO 17664:2017, ISO 17664:2017

Signature:

Place and date (yyyy.mm.dd) of issue:

Nei-Hu, 2021.09.13.

Michael Kuan
President

BenQ Medical Technology Corporation

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Product Detail Information:

Medical Device: Surgical table (Active)

Intended Purpose: Surgical (Operating) tables and accessories are AC-powered or air-powered devices, usually with movable components, intended for use during diagnostic examinations or surgical procedures to support and position a patient.

Product Series	Basic UDI-DI	Product Code	Reference Number
NOT-5600	471987988NOT56007P	Z12011202	研W97-501-000
Dr. Max 5800	471987988DrMax58009V	Z12011202	研W97-502-000
Dr. Max 7000	471987988DrMax700093	Z12011202	研W97-503-000
TriMax 650NS	471987988TriMax650Z4	Z12011202	研W97-504-000
Poseidon Q100	471987988PoseidonQ100A5	Z12011202	研W97-505-000
Poseidon Q200	471987988PoseidonQ200AA	Z12011202	研W97-506-000

The DOC referred to above cover the following models:

NOT- 5600 Series
Optional items: A (Auxiliary control), B (Built-in battery), E (auto leveling), K (Built-in kidney bridge), N (Low tabletop), F (Removable telescopic traction device) and S (Sliding tabletop).

Dr. Max 5800 series
Optional items: A (Auxiliary control), B (Built-in Battery), E (auto leveling), K (Built-in Kidney Bridge), S (Sliding tabletop) and W (Wireless module).

Dr. Max 7000 series
Optional items: A (Auxiliary control), B (Built-in battery), D (Dual plate adjustable and removable gas spring leg sections, K (Built-in Kidney Bridge), M (Manual pump), N (Low tabletop), P (Override pump system), R (Reverse plate), S (Sliding tabletop), W (Wireless module) function code.

TriMax 650NS series
Optional items: B (Built-in battery), K (Built-in kidney bridge), M (Manual pump) and W (Wireless module) function code.

Poseidon Q100 series
Optional items: B (Built-in battery), K (Built-in Kidney Bridge) and W (Wireless module) function code.

Poseidon Q200 series
Optional items: B (Built-in battery), K (Built-in Kidney Bridge) and W (Wireless module) function code

End of list