EC Design Examination Certificate

Certificate No.:	Project No:	Valid Until
10529-2017-CE-RGC-NA-PS Rev 4.0	PRJN-194485-2020-PA-TWN	27 May 2024

This is to certify that:

Sterile Bleeding Management Device and Sterile Wound Dressing

Manufactured by:

BenQ Materials Corporation

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

Has been assessed with respect to:

examination of the design of the product as described in Annex II section 4 of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 21 May 2021

For the issuing office:
Notified Body 2460
DNV Product Assurance AS

Mariann Jeremiassen
Principal Assessor

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as “Forskrift om Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Original Certificate	20-07-2017
1.0	Address correction	11-10-2017
2.0	Editorial change (page number)	11-02-2018
3.0	Extension in scope - new brand name of the existing device added: WATER-JEL ChitoClot Bandage and ChitoSAM™100	21-03-2018
4.0	**Recertification and add the CX series**	**21-05-2021**

Products covered by this Certificate:

Type of medical device and identification no.:	Medical Device Class:	GMDN code:
Sterile Bleeding Management Device and Sterile Wound Dressing - AnsCare ChitoClot Pad: CS series - AnsCare ChitoClot Bandage: CB series - WATER-JEL ChitoClot Bandage - AnsCare ChitoClot Gauze: CG and CX series - ChitoSAM™100 - AnsCare ChitoClot Artery Compression Device: AC series	III	46922
Short description of the Medical Device:		
The wound dressings are intended to be used principally with wounds which have breached the dermis, and can be only healed by secondary intent. The key materials are Poly D-glucosamine and poly N-acetyl- glucosamine derived from Chitosan. The dressings are Gamma-ray sterilized. AnsCare ChitoClot Pad is indicated for use of bleeding wound management. It promotes rapid control of wound bleeding and exudates absorption. In addition, it acts as a protective barrier to prevent wound from contamination. It is indicated for the following wounds including lacerations, abrasions, hemodialysis wound and puncture sites for vascular procedures. AnsCare ChitoClot Bandage/ WATER-JEL ChitoClot Bandage is indicated for use of bleeding		

control. It promotes rapid control of wound bleeding and exudates absorption. In addition, it acts as a protective barrier to prevent wound from abrasion, friction, and contamination. It is indicated for the following wounds including lacerations, abrasions, puncture wounds, and opening contusions.

AnsCare ChitoClot Gauze/ ChitoSAM^{TM}100 is indicated for use of bleeding wound management. It promotes rapid control of moderate to severe bleeding and exudates absorption. It is indicated for the following wounds, including lacerations, abrasions, puncture wounds, and contusions procedures.

AnsCare ChitoClot Artery Compression Device is composed of AnsCare artery compression device and AnsCare ChitoClot Pad. It is indicated for use to stop bleeding from the radial and/or femoral artery after arterial punctures to help promote hemostasis.

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the Notified Body of any intended change of the products detailed above and the Notified Body will assess the changes and decide if the certificate remains valid.

The following may render this Certificate invalid:

- Changes in the design of the products to which this Certificate refers.
- Changes in requirements of the scheme to which this Certificate refers.

Conformity declaration and marking of product

This Certificate must be accompanied with a valid EC Certificate Full Quality Assurance System. When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number.

End of Certificate