Z-MEDICA

EC DECLARATION OF CONFORMITY
(Class III Product)

Z-Medica, LLC declares that the gamma-sterilized kaolin-based QuikClot Hemostatic Dressings medical device product family, specified in the product list below, is in conformity with the essential requirements and provisions of European Union Medical Device Directives 93/42/EEC.

QuikClot Hemostatic Dressings

Description	Catalog No.
QuikClot™ Interventional™ Hemostatic Bandage, no slit with 3M Tegaderm™	183
QuikClot™ Interventional™ Hemostatic Bandage, pre-slit with 3M Tegaderm™	188
QuikClot™ Combat Gauze™ Z-Fold	200
QuikClot™ Combat Gauze™ TraumaPad™	210
QuikClot™ Combat Gauze™ (German)	289
QuikClot™ 2x2 Hemostatic Dressing	302
QuikClot™ 4 x 4 Hemostatic Dressing	301
QuikClot™ TraumaPad™	303
QuikClot™ Combat Gauze™ XL	345
QuikClot™ Combat Gauze™ LE	350
QuikClot™ Interventional™ Hemostatic Bandage, no slit	467Z
QuikClot™ EMS Rolled Gauze	475
QuikClot™ Z-Fold Hemostatic Dressing	632
QuikClot™ Roll Hemostatic Dressing	633
QuikClot™ EMS 4x4 Dressing	636

is represented, for regulatory affairs only, by an Authorized Representative in Europe:

Teleflex Medical
IDA Business and Technology Park
Dublin Rd. Athlone
Co. Westmeath, Ireland

Notified Body Number 2797, BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands. **CE Certificate # 697147 and CE Certificate # 508609.**

The products are subject to the procedures set out in the EU MDD 93/42/EEC.
Classification: Class III - Rule 13, Conformity Assessment Route: Annex II, GMDN: 47917 – Inorganic Haemostatic Agent, Sterile

This declaration is issued under the sole responsibility of Z-Medica, LLC and authorizes Z-Medica, LLC to affix the CE-marking to the products listed herein.

4 Fairfield Blvd.
Wallingford, Connecticut 06492
USA

19-Dec-2023

Place and date of issue *Kelsey Moylan, Sr. Manager, Regulatory Affairs - Product Management*

Z-Medica, LLC
4 Fairfield Boulevard
Wallingford
Connecticut
06492
USA

08 April 2024

Notified Body Confirmation Letter

Reference: EU2023-607/810168

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Z-Medica, LLC
4 Fairfield Boulevard
Wallingford
Connecticut
06492
USA

SRN Number (if available): US-MF-000029799

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR

application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, 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 below:

- 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)

On behalf of BSI Group The Netherlands B.V.,

Graeme Tunbridge
Senior Vice President, Medical Devices

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
QuikClot Interventional Products (Cath Lab Products) **08019020000000000000243KL**	Class III	N/A	CE 697147; NB2797 CE 508609; NB2797
QuikClot Combat Gauze and EMS Products (QuikClot Military, Law Enforcement, and EMS Rolled Gauze Products) **08019020000000000000244KN**	Class III	N/A	CE 697147; NB2797 CE 508609; NB2797
QuikClot Gauze (Hospital Products & EMS 4x4 with X-ray) **08019020000000000000245KQ**	Class III	N/A	CE 697147; NB2797 CE 508609; NB2797

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	Action
2024/04/08	Initial issue