

EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex II Section 4

No.**CE 697147**

Issued To:

**Z-Medica, LLC
4 Fairfield Blvd.
Wallingford
Connecticut
06492
USA**

In respect of:

QuikClot Hemostatic Dressing

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2020-11-12**Date: **2021-04-02**Expiry Date: **2024-05-26**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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Supplementary Information to CE 697147

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
QuikClot Gauze				
301	QuikClot 4x4	10cm x 10cm	Hospital products intended for use as a topical dressing for local management of bleeding wounds such as cuts, lacerations, and abrasions. It may also be used for temporary treatment of severely bleeding wounds such as surgical wounds (operative, post-operative, dermatological, etc) and traumatic injuries.	Class III
302	QuikClot 2x2	5cm x 5cm		Class III
303	QuikClot TraumaPad	30cm x 30cm		Class III
632	QuikClot Z-Fold	7.6cm x 3.7m		Class III
633	QuikClot Roll			Class III
636	EMS 4x4 with x-ray	10cm x 10cm		Class III

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
QuikClot Gauze Cath Lab				
374	QuikClot Radial with DP	2cm x 3.8cm	Intended to be applied topically as an adjunct to manual compression and is indicated for the local management and control of surface bleeding from vascular access sites, percutaneous catheter or tubes utilizing introduction sheaths up to 12 Fr., or 7 Fr. in patients on drug/induced anticoagulant treatment.	Class III
183	QuikClot Interventional, no slit with 3M Tegaderm	3.8cm x 3.8cm		Class III
188	QuikClot Interventional, pre-slit with 3M Tegaderm			Class III
467Z	QuikClot Interventional, no slit			Class III

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
QuikClot Combat Gauze and EMS products				
200	Combat Gauze	7.5cm x 3.7m	Temporary external use to control traumatic bleeding.	Class III
2000	Combat Gauze Polish			Class III
210	Combat Gauze TraumaPad	30.0cm x 30.0cm		Class III
289	Combat Gauze German	7.5cm x 3.7m		Class III
345	Combat Gauze XL	10.2cm x 3.7m		Class III
350	Combat Gauze LE	7.5cm x 3.7m		Class III
473	QuikClot EMS 4x4	10cm x 10cm		Class III
475	QuikClot EMS Roll	7.6cm x 1.2m		Class III

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Certificate History

Date	Reference Number	Action
12 November 2020	9625224	First issue.
Current	3385283	Removal of "PN" prefix from device part numbers to align with format in DoC. Reformatting of part number PN 467-Z to 467Z. Reformatting of part number PN 200-PL to 2000. Addition of new part number: 636. Change to IFU for QuikClot Radial with DP (part number 374) to include additional method of application.

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