

EC Certificate - Full Quality Assurance System

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

No.**CE 607662****Issued To:**

Medeco B.V.
Alexander Flemingstraat 2
Oud-Beijerland
3261 MA
The Netherlands

In respect of:

See certificate scope page.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II 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: **2016-06-24**

Date: **2020-04-17**

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 approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.

Certificate No: CE 607662

Certificate Scope:

The design, manufacture and final inspection of sterile pen needles, sterile enteral pump feeding sets including connectors and adapters, non-sterile gauzes and superabsorbent dressings, sterile non-medicated wound dressings comprising alginate, foam, silicone contact layer, superabsorbent, gauze, non-woven, hydrocolloid and petroleum tulle gras technologies

Those aspects of Annex II concerned with securing and maintaining sterility of wound dressings, plasters, urine collection bags including connecting and fixation materials, syringes and enteral gravity feeding sets including connectors and adapters.

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Supplementary Information to CE 607662

Issued To:

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Number	Device Name	Intended purpose per IFU
Class IIb		
MD 0301	Alginate dressing	Indicated for moderate to heavily exuding chronic and acute wounds including pressure ulcers, leg ulcers, diabetic ulcers, post-operative wounds and donor sites. Can also be used to control minor bleeding in superficial wounds.
	Foam dressing	Indicated for moderate to heavily exuding chronic and acute wounds and may be used throughout the healing process on the following wounds: pressure ulcers, venous leg ulcers, diabetic foot ulcers, lacerations, abrasions, post-operative surgical wounds, superficial and partial thickness burns. Suitable for use under compression bandaging and may be used on cavity wounds as a secondary dressing.

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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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Issued To:

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Number	Device Name	Intended purpose per IFU
Class IIb		
MD 0301	Silicone foam dressing	Indicated for moderate to heavily exuding chronic and acute wounds and may be used throughout the healing process on the following wounds: pressure ulcers, venous leg ulcers, diabetic foot ulcers, lacerations, abrasions, skin tears, donor sites, postoperative surgical wounds, superficial and partial thickness burns. Suitable for use under compression bandaging.
	Hydrocolloid dressing	Indicated for low exuding chronic and acute wounds including pressure ulcers, leg ulcers, burns, donor sites and post-operative wounds. It may also be used as a protective dressing on sites exposed to rubbing and shearing stresses. The dressing can be used in combination with compression therapy.

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Number	Device Name	Intended purpose per IFU
Class IIb		
MD 0301	Silicone wound contact layer	Indicated for use in combination with a secondary absorbent dressing on a wide range of exuding wounds, such as diabetic foot ulcers, pressure ulcers, leg (venous and arterial) ulcers, first- and second-degree burns, surgical wounds and traumatic wounds. It can also be used as wound protective layer on non-exuding wounds and on areas with fragile skin.
	Superabsorbent dressing	Indicated for moderate to heavily exuding chronic and acute wounds and may be used throughout the healing process on leg ulcers, pressure ulcers, oncology wounds, post-operative wounds and traumatic wounds.
Class IIa		
MD 0301	Tulle gras dressing	--
MD 0301	Gauze dressing	--
MD 0301	Non-woven dressing	--
MD 0102	Pen needle	--
MD 0102	Enteral feeding set	--

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Number	Device Name	Intended purpose per IFU
Class Is		
MD 0301	Bandage	--
MD 0301	Film dressing	--
MD 0301	Gauze dressing	--
MD 0301	Non-woven dressing	--
MD 0301	Plaster	--
MD 0301	Waterproof plaster	--
MD 0106	Urine collection bag	--
MD 0106	Needleless syringe	--
MD 0106	Enteral feeding gravity set	--

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12 April 2024

Medeco B.V.
Brandpuntlaan Zuid 14
Bleiswijk
2665 NZ
The Netherlands

To whom it may concern,

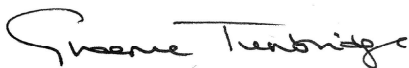
The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	Directive and Annex	Reference Number	Changes approved
CE 607662	93/42/EEC Annex II excluding Section 4	30000136	Change in legal manufacturer address from "Alexander Flemingstraat 2, Oud-Beijerland, 3261 MA, The Netherlands" to "Brandpuntlaan Zuid 14, Bleiswijk, 2665 NZ, The Netherlands".

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,



Graeme Tunbridge
Senior Vice President, Medical Devices