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By Royal Charter

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:

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.

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.

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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EC Cerificate - Full Quality Assurance System

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

Č.:	CE 607662
Vydané pre:	Medeco B.V. Alexander Flemingstraat 2 Oud Beijerland 3261 MA Holandsko

Se zretel´om na:

Návrh, výroba a konečná kontrola sterilných ihiel do pera, sterilných súprav na enterálnu výživu vrátane konektorov a adaptérov, nesterilných gáz a superabsorpčných obväzov, sterilných nemedikovaných obväzov na rany obsahujúcich alginát, penu, silikónovú kontaktnú vrstvu, superabsorpčné, gázové, netkané, hydrokoloidné a petrolejové obväzy.
Tie aspekty prílohy II, ktoré sa týkajú zabezpečenia a udržiavania sterility obväzov na rany, náplastí, vreciek na zber moču vrátane spojovacích a fikačných materiálov, injekčných striekačiek a súprav na enterálnu gravitačnú výživu vrátane konektorov a adaptérov.

na základe nášho preskúmania systému zabezpečenia kvality podľa požiadaviek smernice Rady 93/42/EHS, príloha II, okrem oddielu 4. Systém zabezpečenia kvality spĺňa požiadavky smernice. Na uvedenie výrobkov triedy III na trh sa vyžaduje certifikát podľa prílohy II oddielu 4.

V mene a na účet BSI, notifikovaného orgánu pre uvedenú smernicu (číslo notifikovaného orgánu 2797):

Gary E Slack, Senior Vice President Medical Devices

Prvé vydanie: 2016-06-24 Dátum: 2020-04-17 Dátum skončenia platnosti: 2024-05-26