By Royal Charter

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 754472 R000

Manufacturer: Medeco B.V.

Address:
Brandpuntlaan Zuid 14
Bleiswijk
2665 NZ
The Netherlands

Single Registration Number: NL-MF-000001628

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

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

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2024-04-25**

Current Issue Date: **2026-05-13**

Starting Validity Date: **2026-05-13**

Expiry Date: **2029-04-24**

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Device Schedule: Class III and Class IIb devices

Class IIb	Intended purpose
Sterile Superabsorbent Dressings	Indicated for the management of 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.
Sterile Alginate Dressings	Indicated for the management of chronic and acute wounds including pressure ulcers, leg ulcers, diabetic ulcers, post-operative wounds and donor sites
Sterile Foam Dressings	Indicated for the management of chronic and acute wounds to maintain a moist wound environment in the healing process.
Sterile Hydrocolloid Dressings	Indicated for the management of chronic and acute wounds. May also be used as a protective dressing on sites exposed to rubbing and shearing stresses. Can be used in combination with compression therapy.
Sterile Silicone Wound Contact Layer Dressings	Indicated for use in combination with a secondary absorbent dressing for the management of 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. The dressing can also be used as a wound protective layer on non-exuding wounds on areas with fragile skin.

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Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Sterile and non-sterile Woven and Non-woven Gauzes and Compresses	Class IIa
Sterile Tulle Gras Dressings	Class IIa
Sterile Enteral Feeding Gravity Sets	Class Is
Sterile Needleless Syringes	Class Is
Sterile Drainage and Fluid Collection Devices	Class Is
Sterile Film Dressings	Class Is
Sterile IV Dressings/Plasters	Class Is
Sterile Non-woven Dressings	Class Is
Sterile Bandages	Class Is
Sterile Plasters	Class Is
Sterile Woven and Non-woven Gauzes and Compresses	Class Is
For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.	

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2024-04-25	3493228	Issued
2025-08-27	30430059	Supplemented – Addition of Class IIb devices Sterile Foam Dressings, Sterile Hydrocolloid Dressings and Sterile Silicone Wound Contact Layer Dressings. Addition of Class IIa devices Sterile and non-sterile Woven and Non-woven Gauzes and Compresses and Sterile Tulle Gras Dressings.
Current	30559969	Supplemented – Addition of Class Is device Sterile IV Dressings/Plasters and related subcontractors for manufacturing and sterilisation. Addition of subcontractor for manufacturing and sterilisation of Class IIb device Sterile Superabsorbent Dressings.

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