

## EU Quality Management System Certificate

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

### MDR 754472 R000

**Manufacturer:** Medeco B.V.

**Address:**

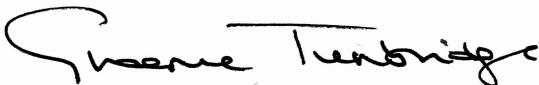
Brandpuntlaan Zuid 14  
Bleiswijk  
2665 NZ  
The Netherlands

**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: **2024-04-25**

Starting Validity Date: **2024-04-25**

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 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 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.

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

Device(s)	Risk Classification
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 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](mailto:Certificate.Verification@bsigroup.com))

Date	Reference Number	Action
Current	3493228	Issued



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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation 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.