

# EU Quality Management System Certificate

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

## MDR 746992 R000

**Manufacturer:** Laboratoires Urgo

**Address:**

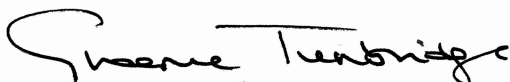
42 Rue de Longvic  
Chenôve  
21300  
France

**Single Registration Number:** FR-MF-000002559

**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: **2022-05-06**

Current Issue Date: **2024-11-01**

Starting Validity Date: **2024-11-01**

Expiry Date: **2027-05-05**

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### Device Schedule: Class III and Class IIb devices

Class III	Intended purpose
Urgotul Ag / Silver	See MDR 764867
Urgotul Ag Lite Border	See MDR 764866
Urgodean Ag Pad / Compresse / Kompresse (standard pouch)	See MDR 764863
Urgodean Ag Pad / Compresse / Kompresse (reinforced pouch)	See MDR 764863
Urgocell Ag / Silver	See MDR 764864
Class IIb	Intended purpose
Contact Layer Wound Dressings	Local treatment of chronic wounds and long-standing acute wounds (TLC-NOSF version) Local treatment of acute and chronic wounds (TLC version)
Non-woven Wound Dressings	Local treatment of chronic wounds and long-standing acute wounds (TLC-NOSF version) Local treatment of acute and chronic wounds (TLC and uncoated version)
Polyurethane Wound Dressings	Local treatment of chronic wounds and long-standing acute wounds (TLC-NOSF version) Local treatment of acute and chronic wounds (TLC version)
Wound Care Laser Surgery Instruments and Accessories	Treatment of surgical scars

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

Device(s)	Risk Classification
Protective devices, Lubricants and Soothing Devices (Sprays, Gels, Fluids and Creams)	Class IIa
Wound Care Clinical Decision Support Software	Class IIa

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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
2022-05-06	3409811	Issued
2022-08-04	3729537	Supplemented – Addition of Barrier sprays for skin and wounds
2023-05-10	3832669	Supplemented – Addition of Wound Care Clinical Decision Support Software Supplemented – Addition of Poly-absorbent fibres dressing with Technology Lipido-Colloid Nano-Oligo Saccharide Factor (with and without adhesive border)
2023-07-12	30000785	Amended – Addition of critical subcontractor for ETO sterilisation Amended – Minor correction to intended purpose for Contact Layer Wound Dressings and Non-woven Wound Dressings Amended – Name change of Flexible wound contact layer dressing with Technology Lipido-Colloid Nano-Oligo Saccharide Factor to Contact Layer Wound Dressings Amended – Name change of Poly-absorbent fibres dressing with Technology Lipido-Colloid Nano-Oligo Saccharide Factor (with and without adhesive border) to Non-woven Wound Dressings Amended – Name change of Barrier sprays for skin and wounds to Protective devices, Lubricants and Soothing Devices (Sprays, Gels, Fluids and Creams) Amended – Update to intended purpose for class IIb devices to reflect revise grouping

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Date	Reference Number	Action
2023-10-13	30007159	Amended – Addition of critical subcontractor for manufacture Supplemented – Addition of Polyurethane Wound Dressings
2023-12-18	30032789	Supplemented – Addition of Urgotul Ag / Silver Supplemented – Addition of Urgotul Ag Lite Border Supplemented – Addition of Urgodean Ag Pad / Compresse / Kompresse (standard pouch) Supplemented – Addition of Urgodean Ag Pad / Compresse / Kompresse (reinforced pouch) Supplemented – Addition of Urgocell Ag / Silver Amended – Addition of crucial supplier for medicinal substance
Current	30268758	Supplemented – Addition of Wound Care Laser Surgery Instruments and Accessories Amended – Addition of critical subcontractor for manufacture Amended – Administrative update to add "and uncoated" in Non-woven wound dressings intended purpose

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