

EC Design-Examination Certificate

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

No. **CE 96718**
Issued To: **Laboratoires Urgo**
42 Rue de Longvic
Chenove
21300
France

In respect of:

Sterile Medicated Wound Dressings with Antimicrobial Silver:
Urgocell Ag/Silver
Urgotul Ag/Silver
Urgocell Ag Border (also known as Urgocell Ag Adhesive)
Urgotul Ag Lite (also known as Urgotul Duo Ag)
Urgotul Ag Lite Border (also known as Urgotul Trio Ag)
UrgoClean Ag Pad

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding 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: **2006-03-29**

Date: **2020-04-17**

Expiry Date: **2024-05-26**

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Catalogue number	Device name	Model type	Intended purpose per IFU	Classification
UM0032	Urgocell Ag/Silver	See table below	UrgoCell Ag/Silver is indicated for the local treatment of exuding wounds at risk or with signs of local infection: chronic wounds (pressure ulcers and leg ulcers) and acute wounds (partial thickness burns, dermabrasions, traumatic wounds, chirurgial wounds, etc).	Class III
UM0030	Urgotul Ag/Silver	See table below	Urgotul Ag/Silver is indicated for the local treatment of wounds at risk or with signs of local infection: chronic wounds (pressure ulcers and leg ulcers) and acute wounds (partial thickness burns, dermabrasions, traumatic wounds, surgical wounds, etc...).	Class III
UM0055	Urgocell Ag Border (also known as Urgocell Ag Adhesive)	See table below	Urgocell Ag Border is indicated for the local treatment of exuding wounds at risk or with signs of local infection: chronic wounds (pressure ulcers and leg ulcers) and acute wounds (partial thickness burns, dermabrasions, traumatic wounds, surgical wounds, etc...).	Class III

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Catalogue number	Device name	Model type	Intended purpose per IFU	Classification
UM0040	Urgotul Ag Lite (also known as Urgotul Duo Ag)	See table below	Urgotul Ag Lite is indicated for the local treatment of low exuding wounds at risk or with signs of local infection: chronic wounds (pressure sores and ulcers) and acute wounds (partial thickness burns, dermal abrasions, traumatic wounds, post operative wounds, etc...).	Class III
UM0057	Urgotul Ag Lite Border (also known as Urgotul Trio Ag)	See table below	Urgotul Ag Lite Border is indicated for the local treatment of low exuding wounds at risk or with signs of local infection: chronic wounds (pressure ulcers and leg ulcers) and acute wounds (partial thickness burns, dermabrasions, traumatic wounds, chirurgial wounds, etc).	Class III
UM0109 UM0137	UrgoClean Ag Pad	See table below	URGOCLEAN Ag Pad is indicated for the local treatment of chronic (leg ulcers, pressure ulcers, diabetic foot ulcers) and acute (burns, traumatic wounds, surgical wounds,) exudative wounds at risk or with signs of local infection, from the debridement stage.	Class III

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Urgotul Ag/Silver

Product Size	Nb of dressings Per Box					
5cm x 5cm	10	1200	-	-	-	-
10cm x 12 cm	3	5	10	12	16	180
15cm x 15cm	3	5	10	-	-	-
15cm x 20cm	5	10	16	-	-	-
20cm x 40cm	5	6	10	50	-	-

Urgotul Ag Lite (also known as Urgotul Duo Ag)

Product Size	Nb of dressings Per Box		
5cm x 7cm	26	-	-
10cm x 12cm	3	16	100
11cm x 11cm	3	16	-
15cm x 15cm	3	-	-
15cm x 20cm	10	16	-

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Urgotul Ag Lite Border (also known as Urgotul Trio Ag)

Product Size	Nb of dressings Per Box				
6.5cm x 10cm	10	16	-	-	-
8cm x 8cm	1	3	10	16	80
10cm x 12cm	1	3	10	16	80

Urgocell Ag/Silver

Product Size	Nb of dressings Per Box			
6cm x 6cm	16	-	-	-
10cm x 10cm	3	10	16	-
10cm x 12cm	3	10	16	120
15cm x 15cm	3	10	-	-
15cm x 20cm	10	16	50	-

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Urgocell Ag Border (also known as Urgocell Ag Adhesive)

Product Size	Nb of dressings Per Box		
13cm x 13cm	10	16	150

UrgoClean Ag Pad

Product Size	Nb of dressings Per Box				
6cm x 6cm	5	10	-	-	-
6cm x 10cm	16	-	-	-	-
10cm x 10cm	3	5	10	16	100
12cm x 10cm	3	5	10	20	100
13cm x 12cm	16	-	-	-	-
15cm x 15cm	3	5	10	16	-
15cm x 20cm	3	5	10	16	-

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Certificate History

Date	Reference Number	Action
29 March 2006	10068745	First Issue.
05 January 2007	10080909	Addition of Urgotul® Duo Ag.
01 October 2007	10088785	Extension of Urgocell Ag's Shelf Life to 3 years. Addition of new product codes.
26 February 2010	10099320	Addition of Urgocell® Ag Adhesive 13 x 13 cm.
20 August 2010	10102990	Addition of Urgotul® Trio Ag product family.
06 June 2011	10123498	Certificate renewal. Simplification of information to remove product codes and presentation formats. Product name updates.
15 May 2012	10123867	Inclusion of alternative packaging configurations for Urgocell Ag/Silver, Urgotul Ag/Silver and Urgotul Duo Ag/Silver.

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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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Date	Reference Number	Action
21 September 2015	10146735 10145215 10130491	Addition of UrgoClean Ag dressings. Addition of BGS Beta-Gamma-Services GmbH & Co KG as subcontractor for e-beam sterilisation activities. Addition of Metalor Technologies France SAS as crucial supplier.
12 April 2016	10159071 10154116 & 10156584	Certificate Renewal. Change to indications and material specification.
09 August 2016	10159933	New quantity of dressings per box added to the UrgoClean Ag range.
25 October 2016	10161754	Change of supplier location and addition of new component to raw material of the adhesive mass for Urgotul Ag Lite Border and Urgocell Ag Border.
30 November 2016	10165050 10161767	Change of liquid paraffin supplier, change to composition of non-woven pad and change of sterilisation dose from 25kGy to 30kGy minimum for UrgoClean Ag. Addition of alternative primary packaging to the 6cm x 6cm, 10cmx10cm, 15cmx15cm and 15cm x 20cm variants of UrgoClean Ag range.

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12 May 2017	10168420 10164061 10164063 10164064	Change of liquid paraffin oil, addition of new mixing process, removal of 'store flat' from IFU, change to analytical test method and change to non-woven pad supplier for Urgotul Ag, Urgotul Ag Lite, Urgotul Ag Lite Border, Urgocell Ag and Urgocell Ag Border. Addition of new dressing sizes for Urgotul Ag and Urgocell Ag. Addition of packaging configuration for Urgotul Ag, Urgotul Ag Lite Border and Urgocell Ag Border.
16 November 2017	8487651	Addition of 20cm x 40cm size to Urgotul Ag/Silver range.
27 February 2019	7779339	Traceable to NB 0086.
21 January 2020	9704199	Addition of Laboratorios Argenol S.L. as crucial supplier. Addition of supplementary page.
Current	3039451	Certificate renewal. Removal of 'silver' for Urgotul Ag Lite and Urgocell Ag Border. Addition of 'pad' for UrgoClean Ag.

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