

# EC Design-Examination Certificate

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

**No.** **CE 707479**  
**Issued To:** **Ansell Healthcare Europe NV**  
**Boulevard International 55**  
**Brussels**  
**B-1070**  
**Belgium**

In respect of:

**Sterile surgeons gloves with Chlorhexidine.**

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):



Albert Roossien, Regulatory Lead

First Issued: **2019-03-15**

Date: **2019-03-20**

Expiry Date: **2024-03-14**

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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 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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## Supplementary Information to CE 707479

Issued To:

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Catalogue Number	Device name	Model Type	Intended purpose per IFU	Classification
353441	Gammex Powder-free with ATM technology	Size 5.5 (25 pairs)	Intended to be worn by operating room personnel to protect a surgical wound from contamination.	Class III
353442		Size 6.0 (25 pairs)		
353443		Size 6.5 (25 pairs)		
353444		Size 7.0 (25 pairs)		
353445		Size 7.5 (25 pairs)		
353446		Size 8.0 (25 pairs)		
353447		Size 8.5 (25 pairs)		
353448		Size 9.0 (25 pairs)		
354111	Gammex Non latex Antimicrobial Surgical gloves	Size 5.5 (25 pairs)	Intended to be worn by operating room personnel to protect a surgical wound from contamination.	Class III
354112		Size 6.0 (25 pairs)		
354113		Size 6.5 (25 pairs)		
354114		Size 7.0 (25 pairs)		
354115		Size 7.5 (25 pairs)		
354116		Size 8.0 (25 pairs)		
354117		Size 8.5 (25 pairs)		
354118		Size 9.0 (25 pairs)		

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## Certificate History

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Date	Reference Number	Action
15 March 2019	9723193	First Issue.
Current	7779336	Traceable to NB 0086.

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