

EC Design-Examination Certificate

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

No.**CE 707479****Issued To:**

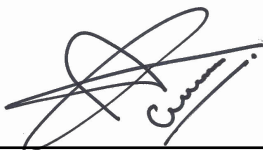
**Ansell Healthcare Europe NV
Boulevard International 55
Brussels
B-1070
Belgium**

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:

Ansell Healthcare Europe NV
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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

Certificate No: **CE 707479**
Date: **2019-03-20**
Issued To: **Ansell Healthcare Europe NV**
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| Date | Reference Number | Action |
|---------------|------------------|-----------------------|
| 15 March 2019 | 9723193 | First Issue. |
| Current | 7779336 | Traceable to NB 0086. |

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