

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No.**CE 01537****Issued To:**

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

In respect of:

Manufacture of sterile surgeons gloves.

Those aspects of Annex V related to securing and maintaining sterility in the manufacture of examination gloves.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III 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: **1997-01-28**

Date: **2020-08-06**

Expiry Date: **2023-01-26**

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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 approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

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Supplementary Information to CE 01537

Issued To:

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Number	Device Name	Intended Purpose per IFU
Class IIa		
MD 0101	Sterile surgeon's glove – Natural Rubber Latex	Intended to be worn by operating room personnel to prevent cross contamination from microbes and body fluids between the patient and wearer.
MD 0101	Sterile surgeon's glove – Synthetic Polyisoprene	
MD 0101	Sterile surgeon's glove – Neoprene	
MD 0101	Sterile surgeon's glove – Hybrid (Polyisoprene/Neoprene)	
MD 0101	Radiation attenuating polyisoprene Sterile Surgical Glove	Intended to be worn by operating room personnel to prevent cross contamination from microbes and body fluids between the patient and wearer, also intended to protect the hands from scattered secondary radiations.
MD 0101	Gammex® Latex Glove- in-Glove™ System	Intended to be worn by operating room personnel to prevent cross contamination from microbes and body fluids between the patient and wearer. Ready for immediate double donning by the clinician.
MD 0101	Gammex® PI Plus Glove-in-Glove™ System	
Class Is		
MD 0101	Examination gloves	Intended to be worn by healthcare personnel for examination/treatment; as a barrier protection against cross contamination and a wide range of chemicals. The gloves are intended for single use.

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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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Subcontractor:	Service(s) supplied
Ansell Lanka (Pvt) Limited Biyagama Export Processing Zone Biyagama Sri Lanka	Manufacture
Ansell N.P, Sdn Bhd Lot 80 & Lot 92 Air Keroh Industrial Estate 75450 Melaka Malaysia	Manufacture
Careglove Global Sdn. Bhd. Lot 17479, Lorong Senawang 3/2 Off Jalan Senawang 3 Senawang Industrial Estate 70450 Seremban, Negeri Sembilan Malaysia	Manufacture

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Subcontractor:	Service(s) supplied
Careplus (M) Sdn. Bhd. Lot 120 & 121, Jalan Senawang 3 Senawang Industrial Estate 70450 Seremban, Negeri Sembilan Malaysia	Manufacture
Grand Ten Holdings Sdn Bhd Plot PT 5754, Jalan 2 Kawasan Perusahaan Bandar Baru Salak Tinggi 43900 Sepang Selangor Malaysia	Radiation (Gamma Sterilization)
H. Essers 4 Zonen International Transport N.V Transportlaan 4 B-3600 Genk Belgium	Secondary Packaging

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Subcontractor:	Service(s) supplied
PGA - Perusahaan Getah Asas Sendirian Berhad Jalan Sungau Sembilang Jeram, 45800 Kula Selangor Selangor Darul Ehsan Malaysia	Manufacture
Primus Gloves Private Limited Plot No. 14-A Cochin Special Economic Zone Kakkanad Kochi 682 037 India	Manufacture
Wear Safe (Malaysia) Sdn. Bhd Lot 1, Leboh Hishameddin Satu North Klang Straits Industrial Area 4200 Port Klang Selangor Malaysia	Manufacture

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Subcontractor:	Service(s) supplied
WRP Asia Pacific Sdn Bhd Lot 1 Jalan 3 Kawasan Perusahaan Bandar Baru Salak Tinggi 43900 Sepang Selangor Malaysia	Manufacture
Yaan Device Co Ltd 9th Floor No. 80, Fu Hsing North Road 10488 Taipei Taiwan	Manufacture

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Certificate History

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 Date: **2020-08-06**
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Date	Reference Number	Action
18 May 2012	7805588	<p>First Issue.</p> <p>Transfer of certificate location from Ansell (UK) Ltd to Ansell Healthcare Europe NV.</p> <p>Addition of significant subcontractors Ansell (UK) Limited.</p> <p>Ad-Corner S.A. and Mpt Med Production and Trading GmbH and removal of significant subcontractors Ansell Lanka (Pvt) Ltd, Ansell (Ambi) Sdn Bhd, Ansell (Thailand) Ltd, J K Ansell Limited, Fuji Latex Co. Ltd, Okamoto Industries, Ansell Healthcare (Australia), Ansell Healthcare Products Inc, Finishing Services PTY Ltd, Ansell Healthcare Europe NV, Enersol Pty Ltd, Condomi Erfurt and Unimil S.A.</p> <p>Change of address for significant subcontractor Ansell SA and removal of 'Administration & Complaints' from services supplied by this subcontractor.</p> <p>Addition of Distribution and Warehousing to services supplied by significant subcontractor DSV Solutions Sp. Z o. o.</p> <p>Change of service supplied by significant subcontractor Wear Safe Malaysia Sdn Bhd from Packaging to Manufacture.</p> <p>Change of service supplied by significant subcontractor Wuhan Jissbon Sanitary Products Co Limited from Packaging to Secondary Packaging.</p> <p>Change of services supplied by significant subcontractor H. Essers 4 Zonen from Packaging to Distribution, Warehousing and Secondary Packaging.</p>

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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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09 November 2012	7911046	Remove Span Packaging Services and Kanjur Naturals as a significant subcontractor.
28 January 2013	7919868	Certificate renewal and change to scope to include sterile surgeons gloves with Chlorhexidine.
03 June 2015	8137564	Update to subcontractors list: addition of Ansell Lanka Ltd, Delsol products Limited and Evonik Degussa GmbH; removal of Aexxdis, Ansell SA and Cex International S.A.
07 February 2017	8472284	Removal of subcontractors Ansell (UK) Limited, Tamworth, UK and Ansell Shah Alam Sdn Bhd, Shah Alam, Malaysia. Change of subcontractor name from 'IDS Manufacturing Limited' to 'LF Beauty (Thailand) Limited'. Reduction of certificate scope to remove spermicidal nonoxynol 9.

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27 April 2019	8775850	<p>Certificate renewal.</p> <p>Reduction of certificate scope to remove "natural rubber latex male condoms lubricated with Lidocaine Hydrochloride and Benzocaine" and "personal medical lubricants".</p> <p>Removal of subcontractors Ad-Corner S.A, Delsol Products Limited, DSV Solutions SP. Zo.o., KOHRS Medical Supplies (Pty.) Ltd, LF Beauty (Thailand) Limited, Marken Kosmetik Service GmbH, Mpt Med Production and Trading GmbH, Suretex Limited, Suretex Prophylatics (India) Ltd and Wuhan Jissbon Sanitary Products Co Limited.</p> <p>Removal of the activities of Distribution and Warehousing for the subcontractor H. Essers 4 Zonen International.</p>
15 March 2019	9723098	<p>Scope reduction to remove " Manufacture of sterile surgeons gloves with Chlorhexidine".</p> <p>The following subcontractor has been removed linked to the scope reduction: Evonik Deggusa GmbH.</p>
20 March 2019	7779336	Traceable to NB 0086.
30 June 2020	3171706	Update supplementary product information table with addition of Glove-in-Glove System devices and expand the list by clearly identifying all the products covered under this certificate scope.

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Date	Reference Number	Action
Current	3269456	Addition of subcontractors Careglove Global Sdn. Bhd., Careplus (M) Sdn. Bhd., Grand Ten Holdings Sdn. Bhd., and Primus Gloves Private Limited

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