

EC Certificate - Production Quality Assurance

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

No. CE 98952
Issued To: ASO LLC
300 Sarasota Center Boulevard
Sarasota
Florida
34240
USA

In respect of:

The manufacture of sterile and non-sterile hydrocolloid bandages

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: **2005-11-07**

Date: **2020-05-13**

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

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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.

This certificate was issued electronically and is bound by the conditions of the contract.

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Supplementary Information to CE 98952

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NBOG code(s)	Device Name	Intended purpose per IFU
Class IIa		
MD0301	Hydrocolloid bandages	Not applicable for Class IIa

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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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List of Significant Subcontractors

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

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Subcontractor:	Service(s) supplied
ASO Europe Bijsterhuizen 1160E 6546 AS Nijmegen The Netherlands	EU Representative
EUROMED, Inc. 25 Corporate Drive Orangeburg New York, 10962 USA	Control of Sterilization Manufacture
Synergy Health AST, LLC 7225 North Noah Drive Saxonburg Pennsylvania 16056 USA	Radiation (E Beam Sterilization)
VALUEPACK Europe Sp. z o. o. ul. Boleslaw Prusa 8A 67-300 Szprotawa Poland	Packaging

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EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 98952**
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Date	Reference Number	Action
7 November 2005		First issue following transfer from TÜV Rheinland, Certificate Numbers HD60004674 and DD60004676
15 November 2010	7602410	Renewal. Update to company name and zip code. Updated address for subcontractor Euromed Inc. Removal of subcontractors Titan Scan Technologies, CA and International Sterilization Laboratory, FL. Addition of new subcontractors: BeamOne LLC and E-beam Services Inc, NJ. Addition of EU Rep, ASO Europe
5 December 2012	7911196	Extension of scope to include non sterile hydrocolloid bandages Sterilisation subcontractor updates
04 November 2015	8412010	Certificate renewal and removal of E-Beam Services Inc. as significant sub-contractor.
28 February 2019	7781263	Traceable to NB 0086.
25 September 2019	9775120	Addition of subcontractor VALUEPACK Europe Sp. Z o.o. Removal of subcontractors: Synergy Health AST, Denver & Synergy Health AST, Lima
Current	3159327	Certificate renewal.