By Royal Charter

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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Supplementary Information to CE 98952

Issued To:

ASO LLC
300 Sarasota Center Boulevard
Sarasota
Florida
34240
USA

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

First Issued: **2005-11-07** Date: **2020-05-13** Expiry Date: **2024-05-26**

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

List of Significant Subcontractors

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

Certificate No:	**CE 98952**
Date:	**2020-05-13**
Issued To:	**ASO LLC** **300 Sarasota Center Boulevard** **Sarasota** **Florida** **34240** **USA**

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. Boleslawa Prusa 8A 67-300 Szprotawa Poland	**Packaging**

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bsi.

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EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 98952**

Date: **2020-05-13**

Issued To: **ASO LLC**
300 Sarasota Center Boulevard
Sarasota
Florida
34240
USA

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.