

EC Certificate - Production Quality Assurance

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

No. CE 556273
Issued To: **DMS Holdings, Inc., dba MABIS
Healthcare, dba Duro-Med Industries,
dba Briggs Medical Service Co.
1931 Norman Drive
Waukegan
Illinois
60085
USA**

In respect of:

Manufacture of Amniotic Membrane Perforators, umbilical cord clamps and Plastibell Circumcision Devices

Those aspects of Annex V relating to securing and maintaining sterility in the manufacture of pediatric urine specimen collectors

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: **2010-02-10**

Date: **2020-01-14**

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 556273

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NBOG code(s)	Device description	Intended purpose
Class IIa		
MD 0106	Amnihook Amniotic Membrane Perforator	N/A for Class IIa devices
MD 0106	PlastiBell Circumcision Device	N/A for Class IIa devices
MD 0106	Double Grip Umbilical Cord Clamp	N/A for Class IIa devices
Class Is		
MD 0100	U-Bag Single Specimen Collector	N/A for Class Is devices
MD 0100	U-Bag 24 hour Specimen Collector	N/A for Class Is devices
MD 0100	Premier U-Bag	N/A for Class Is devices

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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
Emergo Prinsessegracht 20 2514 AP The Hague The Netherlands	EU Representative
Hollister Incorporated 1502 East LaHarpe Kirksville MO 63501 USA	Manufacture
Steris Applied Sterilization Technologies, Isomedix Operations Inc., 2072 Southport Road Spartanburg South Carolina 29306 USA	ETO Sterilization

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EC Certificate - Production Quality Assurance Certificate History

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Date	Reference Number	Action
10 February 2010	7454434	First issue
08 July 2015	8315188	Certificate Renewal. Update of significant subcontractor for ETO sterilisation to Sterigenics International Inc., 2015 Spring Road, Suite 650, Oak Brook, Illinois, 60523,USA. Change of address for significant subcontractor Hollister Incorporated, to 1502 East LaHarpe, Kirksville, MO 63501, USA
21 September 2015	8406526	Administrative update to company name.
19 May 2017	8726480	Change of address for subcontractor Emergo Europe, to Prinsessegracht 20, 2514 AP The Hauge, The Netherlands.
25 February 2019	7781396	Traceable to NB 0086.
19 December 2019	3084783	Removal of Sterigenics Oak Brook Illinois facility. Addition of significant subcontractor Steris Applied Sterilization Technologies, Isomedix Operations Inc., in Spartanburg South Carolina for ETO Sterilization.
Current	9772685	Renewal.