By Royal Charter

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**

...making excellence a habit.™

EC Certificate - Production Quality Assurance

Supplementary Information to 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

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

First Issued: **2010-02-10** Date: **2020-01-14** Expiry Date: **2024-05-26**

...making excellence a habit.™

By Royal Charter

EC Certificate - Production Quality Assurance

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 556273**
Date:	**2020-01-14**
Issued To:	**DMS Holdings, Inc., dba MABIS Healthcare, dba Duro-Med Industries, dba Briggs Medical Service Co. 1931 Norman Drive Waukegan Illinois 60085 USA**

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**

...making excellence a habit.™

EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 556273**

Date: **2020-01-14**

Issued To: **DMS Holdings, Inc., dba MABIS Healthcare, dba Duro-Med Industries, dba Briggs Medical Service Co.**
1931 Norman Drive
Waukegan
Illinois
60085
USA

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.