16/02/2021

LETTER OF DISTRIBUTION

To Whom It May Concern,

This letter is to serve notice that GBG-MLD SRL Global Biomarketing Group, located at str. Tighina, 65, of. 607 MD2001 Chisinau, Municipiul Chisinau, Moldova is authorized to distribute the Helena Biosciences Europe Haemostasis and Electrophoresis range of products in the whole Republic of Moldova territory. As such, GBG-MLD SRL Global Biomarketing Group is responsible for promotion, support, installation, and after-sales service for Helena Biosciences Europe products.

GBG-MLD SRL Global Biomarketing Group will maintain appropriate, up-to-date and accurate records to enable the immediate recall of any Products or batches of Products. These records shall include records of deliveries to customers (including batch numbers, expiry dates, delivery date, name and address of customer, telephone number, fax number and e-mail address). These records should be kept for a minimum of one year past the expiry of the product that has been delivered.

This agreement is effective for a period of 3 years from the date of this letter, unless terminated by either party by giving 90 days notice, and can be extended through the mutual agreement of both parties based on sales performance.

Sincerely,

Dmitri Alexandrov

International Business Manager

Helena Biosciences Europe (UK)

Digitally signed by Ceaicovschi Tudor
Date: 2022.10.21 13:47:18 EEST
Reason: MoldSign Signature
Location: Moldova

Helena Biosciences Europe

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Gateshead, Tyne and Wear, NE11 0SD, United Kingdom

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Declaration of Conformity

HL-7-0667DC DOI 2015/08 (1)

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro* Diagnostic Medical Devices & CE marking.

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

Product Code	Description	GMDN Classification Code
100100	SAS-MX SP-10 Kit	53967
100200	SAS-MX SP-10 SB Kit	53967
100400	SAS-MX IFE-2 Kit	53967
100500	SAS-MX Urine Analysis-10 Kit	53967
100700	SAS-MX Acid Hb Kit	53967
100800	SAS-MX Alk Hb Kit	53967
100900	SAS Hb IEF Kit	53967
101200	SAS-MX Lipo Kit	53967
101300	SAS-MX Hi-Res Kit	53967
102300	SAS-MX IEP Kit	53967
200100	SAS-1 SP-24 Kit	53967
200100SP	SAS-1 SP-24 Kit	53967
200200	SAS-1 SP-24 SB Kit	53967
200200SP	SAS-1 SP-24 SB Kit	53967
200400	SAS-1 Urine Analysis Kit	53967
200700	SAS-1 Hi-Res-12 Kit	53967
200900	SAS-1 Alk Hb Kit	53967
201000	SAS-1 Acid Hb Kit	53967
201100	SAS-1 Lipo Kit	53967
300100	SAS-3 SP-60 Kit	53967
300105	SAS-3 SP-80/100 Kit	53967
300200	SAS-3 SP-60 SB Kit	53967
300205	SAS-3 SP-80/100 SB Kit	53967
300400	SAS-3 Urine Analysis Kit	53967
300700	SAS-3 Hi-Res Kit	53967
300900	SAS-3 Alk Hb Kit	53967

Declaration of Conformity

HL-7-0667DC DOI 2015/08 (1)

Product Code	Description	GMDN Classification Code
102206	SAS Kappa IEF Kit	53970
102207	SAS Lambda IEF Kit	53970
102208	SAS Free Kappa IEF Kit	53970
102209	SAS Free Lambda IEF Kit	53970
3151	Helena Biosciences IFE Antisera Kit II	53970
9231	IEP IgA Antiserum	53762
9232	IEP IgG Antiserum	53791
9233	IEP Whole Serum Antiserum	57308
9234	IEP IgM Antiserum	53798
9236	IEP GAM Antiserum	57308
9249	IEP IgD Antiserum	53774
9250	IEP IgE Antiserum	58780
9257	IEP Igλ Antiserum	57325
9262	IEP Igκ Antiserum	57325
9409	IgD Antiserum	53774
9410	IgE Antiserum	53780
9412	Free Kappa Antiserum	57325
9413	Free Lambda Antiserum	57325
220100	Urine Total Antiserum	57308
220200	Urine Micro Antiserum	57308
220300	Urine Macro Antiserum	57308
220400	GAM Antiserum	57308
220500	Free Kappa Antiserum	57325
220600	Free Lambda Antiserum	57325
220700	Kappa Antiserum	57325
220800	Lambda Antiserum	57325
220900	Urine Pent/Alb Antiserum	57308
221000	Urine Penta Antiserum	57308
221100	Serum Fixative	53970
221400	Serum Fixative 2	53970
320100	Urine Total Antiserum	57308
320200	Urine Micro Antiserum	57308
320300	Urine Macro Antiserum	57308
320400	GAM Antiserum	57308
320500	Free Kappa Antiserum	57325
320600	Free Lambda Antiserum	57325
320700	Kappa Antiserum	57325
320800	Lambda Antiserum	57325
320900	Urine Pent/Alb Antiserum	57308
321000	Urine Penta Antiserum	57308

Declaration of Conformity

HL-7-0667DC DOI 2015/08 (1)

Product Code	Description	GMDN Classification Code
321100	Serum Fixative	53970
321200	Pentavalent Screen Antiserum	57308
321300	Pentavalent Screen Antiserum	57308
321400	Serum Fixative 2	53970
3218	Cholesterol Control	53969
5069	Lipotrol Control	53969
5134	CK/LD Control	53969
5141	High-Res Protein Marker	53969
5328	AA2 Hemo Control	53969
5329	ASA2 Hemo Control	53969
5330	AFSA2 Hemo Control	53969
5331	AFSC Hemo Control	53969
5333	HbA2 Quik Column Control Abnormal	59803
5339	HbA2 Quik Column Control Normal	59803
7024	Kemtrol Serum Control – Normal Kit	53969
7025	Kemtrol Serum Control – Abnormal Kit	53969
9400	Immunofixation Control	53969
102210	IgG IEF Control	53969
102010	Alk Phos Control	53969
3021	Titan III-Hb	53967
3022	Titan III-Hb	53967
3023	Titan III-SP	53967
3024	Titan III-SP	53967
3033	Titan III-SP	53967
5334	Sickle-Thal Kit	59807
5341	Beta-Thal HbA2 Kit	59807

Declaration of Conformity

HL-7-0667DC DOI 2015/08 (1)

Product Code	Description	GMDN Classification Code
2010	ProtoFluor-Z Calibrator Low	41744
2011	ProtoFluor-Z Calibrator High	41744
2012	ProtoFluor-Z Reagent	53538
3049	SAS-MX IEP Stain	53970
3100	REP PREP	53970
3100IT	REP PREP	53970
5005	Clear Aid	53970
5016	Electra B1 Buffer	53970
5061	ColoScreen Kit	54547
5062	ColoScreen Kit	54547
5064	ColoScreen Kit	54547
5090	Zip Zone Prep	53970
5127	Haemolysate Reagent	53970
5127SGH	Haemolysate Reagent	53970
5332	HbS Solubility Screening Kit	59807
5526	Ponceau S	53970
5802	Supre Heme Buffer	53970
5805	Electra HR Buffer	53970
200406	SAS-1 Pentavalent Screen Accessory Kit	53970
211100	SAS-M1 Accessory Pack - 6 Sample	53970
211200	SAS-M1 Accessory Pack - 12 Sample	53970
211300	SAS-M1 Accessory Pack - IFE 1	53970
300315	Cryokit	53711
300406	SAS-3 Pentavalent Screen Accessory Kit	53970
310210	SAS Urine Protein Accessory Kit	53970
312100	SAS Supplementary Destain	53970
312200	SAS Supplementary Wash Additive	53970
312400	SAS-5 Wash Solution	58236
312500	SAS IFE Sample Diluent	58237

Declaration of Conformity

HL-7-0667DC DOI 2015/08 (1)

Product Code	Description	GMDN Classification Code
100300	SAS-MX IFE-1 Kit	53967
Which is a multiple part kit comprising:		
100301	SAS-MX IFE-1 Kit	53970
100300A	SAS-MX IFE-1 Kit	53970
100600	SAS-MX Urine IFE-1 Kit	53967
Which is a multiple part kit comprising:		
100601	SAS-MX Urine IFE-1 Kit	53970
100600A	SAS-MX Urine IFE-1 Kit	53970
101000	SAS-MX HDL-10 Kit	53967
Which is a multiple part kit comprising:		
101001	SAS-MX HDL-10 Kit	53970
101002	SAS-MX HDL-10 Kit	53970
101800	SAS-MX CK Vis Kit	53967
Which is a multiple part kit comprising:		
101801	SAS-MX CK Vis Kit	53970
101802	SAS-MX CK Vis Kit	53970
101900	SAS-MX LD Vis Kit	53967
Which is a multiple part kit comprising:		
101901	SAS-MX LD Vis Kit	53970
101902	SAS-MX LD Vis Kit	53970
102000	SAS-MX Alk Phos Kit	53967
Which is a multiple part kit comprising:		
102001	SAS-MX Alk Phos Kit	53970
102002	SAS-MX Alk Phos Kit	53970
102100	SAS IgG IEF Kit	53967
Which is a multiple part kit comprising:		
102201	SAS IgG IEF Kit	53970
102203	SAS IgG IEF Kit	53970
102200	SAS IgG IEF Kit	53967
Which is a multiple part kit comprising:		
102201	SAS IgG IEF Kit	53970
102202	SAS IgG IEF Kit	53970

Declaration of Conformity

HL-7-0667DC DOI 2015/08 (1)

Product Code	Description	GMDN Classification Code
103100	SAS Transferrin IEF Kit	53967
Which is a multiple part kit comprising:		
103101	SAS Transferrin IEF Kit	53970
103102	SAS Transferrin IEF Kit	53970
104100	SAS IgG IEF Plus Kit	53967
Which is a multiple part kit comprising:		
104201	SAS IgG IEF Plus Kit	53970
104203	SAS IgG IEF Plus Kit	53970
104200	SAS IgG IEF Plus Kit	53967
Which is a multiple part kit comprising:		
104201	SAS IgG IEF Plus Kit	53970
104202	SAS IgG IEF Plus Kit	53970
105100	SAS Alpha-1-Antitrypsin IEF Kit	53967
Which is a multiple part kit comprising:		
105101	SAS Alpha-1-Antitrypsin IEF Kit	53970
105102	SAS Alpha-1-Antitrypsin IEF Kit	53970
200300	SAS-1 IFE-4 Kit	53967
Which is a multiple part kit comprising:		
200301	SAS-1 IFE-4 Kit	53970
200300A	SAS-1 IFE-4 Kit	53970
200500	SAS-1 HDL-12 Kit	53967
Which is a multiple part kit comprising:		
200501	SAS-1 HDL-12 Kit	53970
200502	SAS-1 HDL-12 Kit	53970
200600	SAS-1 Cholesterol Profile Kit	53967
Which is a multiple part kit comprising:		
200601	SAS-1 Cholesterol Profile Kit	53970
200602	SAS-1 Cholesterol Profile Kit	53970
200800	SAS-1 Alk Phos Kit	53967
Which is a multiple part kit comprising:		
200801	SAS-1 Alk Phos Kit	53970
200802	SAS-1 Alk Phos Kit	53970

Declaration of Conformity

HL-7-0667DC DOI 2015/08 (1)

Product Code	Description	GMDN Classification Code
201200	SAS-1 CK Vis Kit	53967
Which is a multiple part kit comprising:		
201201	SAS-1 CK Vis Kit	53970
101802	SAS-1 CK Vis Kit	53970
201300	SAS-1 LD Vis Kit	53967
Which is a multiple part kit comprising:		
201301	SAS-1 LD Vis Kit	53970
201302	SAS-1 LD Vis Kit	53970
300300	SAS-3 IFE-9 Kit	53967
Which is a multiple part kit comprising:		
300301	SAS-3 IFE-9 Kit	53970
300300A	SAS-3 IFE-9 Kit	53970
300500	SAS-3 HDL Kit	53967
Which is a multiple part kit comprising:		
300501	SAS-3 HDL Kit	53970
300502	SAS-3 HDL Kit	53970
300600	SAS-3 Cholesterol Profile Kit	53967
Which is a multiple part kit comprising:		
300601	SAS-3 Cholesterol Profile Kit	53970
300602	SAS-3 Cholesterol Profile Kit	53970
300800	SAS-3 Alk Phos Kit	53967
Which is a multiple part kit comprising:		
300801	SAS-3 Alk Phos Kit	53970
300802	SAS-3 Alk Phos Kit	53970
2000	ProtoFluor-Z Reagent Kit	53538
Which is a multiple part kit comprising:		
2000/1	ProtoFluor-Z Reagent Kit	53538
30301SA	ProtoFluor-Z Reagent Kit	41744

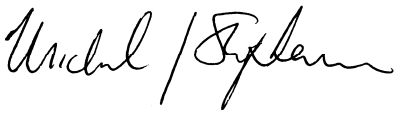
Declaration of Conformity

HL-7-0667DC DOI 2015/08 (1)

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson

Title: Managing Director

Signed: 

Date: 13 Aug 2015

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United Kingdom

Declaration of Conformity

HL-7-0408DC DOI 2015/08 (3)

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro* Diagnostic Medical Devices & CE marking.

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

Product Code	Description	GMDN Classification Code
200100	SAS-1 SP-24 Kit	53967

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson Title: Managing Director

Signed: Date: 14 Aug 2015

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Helena Biosciences Europe
Queensway South, Team Valley Trading Estate,
Gateshead, Tyne and Wear, NE11 0SD,
United Kingdom

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Helena Laboratories (UK) Ltd
trading as Helena Biosciences Europe
Queensway South
Team Valley Trading Estate
Gateshead
Tyne and Wear
NE11 0SD
United Kingdom

Holds Certificate Number: **MD 69326**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The design, manufacture, supply, servicing and repair of in-vitro diagnostic devices, molecular biology products, immunochemistry products and medical laboratory equipment and consumables.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2002-10-25
Latest Revision Date: 2021-04-13

Effective Date: 2021-04-14
Expiry Date: 2024-04-13

...making excellence a habit.™

Certificate No: **MD 69326**

Location	Registered Activities
Helena Laboratories (UK) Ltd trading as Helena Biosciences Europe Sunderland Enterprise Park Colima Avenue Sunderland SR5 3XB United Kingdom	The design, manufacture, supply, servicing and repair of in-vitro diagnostic devices, molecular biology products, immunochemistry products and medical laboratory equipment and consumables.
Helena Laboratories (UK) Ltd trading as Helena Biosciences Europe Queensway South Team Valley Trading Estate Gateshead Tyne and Wear NE11 0SD United Kingdom	The design, manufacture, supply, servicing and repair of in-vitro diagnostic devices, molecular biology products, immunochemistry products and medical laboratory equipment and consumables.

Original Registration Date: 2002-10-25

Effective Date: 2021-04-14

Latest Revision Date: 2021-04-13

Expiry Date: 2024-04-13

Training certificate

helena
Biosciences Europe

This is to certify that

Sergiu Sorocovici

from

IM Global Biomarketing Group

has received training on the following:

Electrophoresis products: SAS-1/2,V8
Haemostasis products: C-series, AC-4, AggRAM and reagents
Service training: AC-4

Signed:

Helena Biosciences Europe (UK) • Helena Biosciences Europe (UK) • helena Biosciences Europe

Date: 31st October - 4th November 2011

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