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:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2002-10-25
Effective Date: 2024-04-14
Latest Revision Date: 2024-03-26
Expiry Date: 2027-04-13

UKAS MANAGEMENT SYSTEMS 0003

Digitally signed by Ceaicovschi Tudor
Date: 2025.12.13 09:24:26 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

...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

Latest Revision Date: 2024-03-26

Effective Date: 2024-04-14

Expiry Date: 2027-04-13

Declaration of Conformity

HL-7- 0135 DC DOI 2013/10 (6)

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
5183	Routine Control SA	30590

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: 31st October 2013

Tel +44 (0)191 482 8440
Fax +44 (0)191 482 8442
info@helena-biosciences.com
www.helena-biosciences.com

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

Declaration of Conformity

HL-7-0136DC DOI 2015/07 (6)

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
5185	Calibration Plasma	55995

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: 28 Jul 2015

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United Kingdom

Declaration of Conformity

HL-7- 0137 DC DOI 2013/10 (6)

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
5186	Routine Control N	30590

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: 31st October 2013

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United Kingdom

Declaration of Conformity

HL-7- 0138 DC DOI 2013/10 (6)

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
5187	Routine Control A	30590

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: 31st October 2013

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United Kingdom

Declaration of Conformity

HL-7- 0163 DC DOI 2014/05 (8)

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
5265	Thromboplastin LI	55983
5265H	Thromboplastin LI	55983
5267	Thromboplastin LI	55983
5269	Thromboplastin LI	55983

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: 07 May 2014

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United Kingdom

Declaration of Conformity

HL-7- 0512 DC DOI 2013/08 (4)

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
5556	Clauss Fibrinogen 50	55997
5556H	Clauss Fibrinogen 50	55997

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: 05 Aug 2013

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THE REPUBLIC OF TÜRKİYE
MINISTRY OF HEALTH
MEDICINES AND MEDICAL DEVICES AGENCY OF TÜRKİYE

Certificate No: 368309

Date of Issue : 3 October 2023

CERTIFICATE OF FREE SALE

To whom it may concern,

It is hereby certified that the products detailed in the attached schedule, which are manufactured by "BİOTA DİAGNOSTİK SAĞLIK HİZMETLERİ SANAYİ VE TİCARET LİMİTED ŞİRKETİ" (*Atatürk Mh. Kerembey Sk. No:3/3 ATAŞEHİR İSTANBUL*), have been affixed with the CE mark in accordance with Medical Device Directives of the European Union (EU) and are freely sold in Türkiye and EU.

This certificate is issued to be given to the relevant competent authorities of "Romania" and is valid for 36 months from the date of issue.

Yours sincerely,

Ömer Faruk KURU
Head of Medical Devices
Registration and Coordination Department

This certificate consists of 3 page/s and 16 products. The products listed in the attached schedule are registered from the date of issuance of this certificate and information about the current status of these products is accessible through

UTS
ÜRÜN TAKİP SİSTEMİ

https://utsuygulama.saglik.gov.tr/UTS/vatandas#/vatTibbiCihazListele.

Address: Sögütözü Mahallesi, 2176. Sokak No:5 06520 Çankaya/ANKARA
Phone: +90 312 218 30 00 Fax: +90 312 218 34 60 https://www.titck.gov.tr

Date of Issue : 3 October 2023

PRODUCT SCHEDULE

#	Barkod	Brand	Label Name	Reference No / Version / Model	GMDN Code
1	8684308520020	BİOTA	VABIO360 Automatic Blood Count Analyzer	VABIO360	35476
2	8684308520037	BİOTA	VABIO580 Automatic Blood Count Analyzer	VABIO580	35476
3	8684308520044	BİOTA	VABIO360 Plus Automatic Blood Count Analyzer	VABIO360+	35476
4	8684308520051	BİOTA	VABIO360 Diluent (20l)	VA-360D	58237
5	8684308520068	BİOTA	VABIO360 Lyse (500 ml)	VA-360L	17123
6	8684308520075	BİOTA	VABIO360 Cleanser (50 ml)	VA-360C	17123
7	8684308520082	BİOTA	VABIO580 Diluent (20 L)	VA-580D	58237
8	8684308520099	BİOTA	VABIO580 L1 Lyse (500 ML)	VA-580L1	17123
9	8684308520105	BİOTA	VABIO580 L2 Lyse (1L)	VA-580L2	17123
10	8684308520112	BİOTA	VABIO580 LH Lyse (500 ML)	VA-580LH	17123
11	8684308520129	BİOTA	VABIO580 Cleanser (50 ml)	VA-580C	17123
12	8684308520136	BİOTA	SABIO140 Automatic Sedimentation Analyzer	SABIO140	56691
13	8684308520143	BİOTA	SABIO JR Automatic Sedimentation Analyzer	SABIO JR	56691
14	8684308520150	SABIO	ESR TEST CARD (1000 TESTS)	SA-TD1000	56691
15	8684308520167	SABIO	ESR TEST CARD (5000 TESTS)	SA-TD5000	56691

Product list to Free Sales Certificate no. 368309

Date of Issue : 3 October 2023

16	8684308520174	SABIO	ESR TEST CARD (10000 TESTS)	SA-TD10000	56691

End of product schedule

Product list to Free Sales Certificate no. 368309

BIOTA
DIAGNOSTIK / AN EXPORT COMPANY

DECLARATION OF CONFORMITY

BIOTA DIAGNOSTIK SAGLIK HIZMETLERI SAN. VE TIC. LTD. STI.

Address : Ataturk Mah. Kerembey Sok.
No:3/3, 34758-Atasehir
Istanbul/Turkey
Phone : +90 212 2485264
E-mail : info@biotadiagnostik.com

We hereby declarate that the below mentioned products meet provisions of the Council Regulation (EU) 2017/746 Invitro Medical Devices. All supporting documentation is retained under the premises of the manufacturer.

Description Of The Product	**:** ESR Analyser
Product Brand	**:** SABIO
Product Type/Model	**:** SABIO140 Automated ESR Analyser (Running directly from EDTA samples) and SABIO140 Test Cards (SA-TD1000, SA-TD5000, SA-TD10000)
Classification	**:** Class A, according to Annex VIII of IVD (EU) 2017/746

General Applicable Directives
Invitro Diagnostic Directive council regulations (**EU) 2017/746** concerning in vitro diagnostic instruments

Standards
All applicable harmonized standards published in the official journal of the European Communities: EN13612:2002; EN ISO 13485, EN 61010-1:20010; EN61010-2-101:2002; EN61326-1:2013; EN61326-2-6:2013; EN62304:2008; EN62366:2008; EN13640:2002

Date Of Issue **:** 20.06.2019

Signature :

BIOTA DİAGNOSTİK SAĞLIK
HİZ. SAN. VE TİC. LTD. ŞTİ.
Atatürk Mah. Kerembey Sok No.3/3
Ataşehir - İstanbul
Kozyatağı V.D. 722 049 1247

Name **:** Erdal Güntürkün
Position **:** CEO