Declaration of Conformity

HL-7-DC-0408 Rev. 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
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: C.J. Sandercock Title: QA and Regulatory Affairs Officer

Signed: Date: 23 Apr 2020

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7812 HZ Emmen
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Digitally signed by Ceaicovschi Tudor
Date: 2024.01.04 10:54:55 EET
Reason: MoldSign Signature
Location: Moldova

Declaration of Conformity

HL-7-DC-0304 Rev. 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
7024	Kemtrol Serum Control - Normal Kit	53969

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

Full Name: C.J. Sandercock Title: QA and Regulatory Affairs Officer

Signed: Date: 22 Apr 2020

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Declaration of Conformity

HL-7-DC-0305 Rev. 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
7025	Kemtrol Serum Control - Abnormal Kit	53969

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

Full Name: C.J. Sandercock Title: QA and Regulatory Affairs Officer

Signed: Date: 23 Apr 2020

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Declaration of Conformity

HL-7-DC-0420 Rev. 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
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

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

Full Name: C.J. Sandercock Title: QA and Regulatory Affairs Officer

Signed: Date: 27 Apr 2020

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Declaration of Conformity

HL-7-DC-0133 Rev. 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
5134	CK/LD Control	53969

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

Full Name: C.J. Sandercock Title: QA and Regulatory Affairs Officer

Signed: Date: 21 Apr 2020

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Declaration of Conformity

HL-7-DC-0418 Rev. 5

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
201100	SAS-1 Lipo Kit	53967

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

Full Name: C.J. Sandercock Title: QA and Regulatory Affairs Officer

Signed: Date: 21 Apr 2020

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Declaration of Conformity

HL-7-DC-0129 Rev. 5

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
5069	Lipotrol Control	53969

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

Full Name: C.J. Sandercock Title: QA and Regulatory Affairs Officer

Signed: Date: 23 Apr 2020

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Declaration of Conformity

HL-7-DC-0414 Rev. 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
200700	SAS-1 Hi-Res-12 Kit	53967

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

Full Name: C.J. Sandercock Title: QA and Regulatory Affairs Officer

Signed: Date: 21 Apr 2020

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helena
Biosciences Europe

To: Medicines and Medical Devices Agency

We, Helena Laboratories (U.K.) Limited, trading as Helena Biosciences Europe

having a registered office at Unit B, M361, Queensway South, Team Valley Trading Estate, Gateshead, Tyne And Wear, NE11 0SD, assign "GBG-MLD" SRL, having a registered office at Str. Albisoara 64/2, Chisinau MD -2005, Moldova, as

Authorized representative in correspondence with the conditions of LAW No. 102 from 09.06.2017 regarding medical devices.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

Place: Gateshead Date: 17/10/2022

Signed:

Helena Biosciences Europe

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

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