Anexa 51 la Formularul Specificatie Tehnica

Coagulometru portabil Cod 151120

Model C-1X (Helena Biscience, Marea Britanie)

Specificatia tehnica solicitata	Specificatia tehnica ofertata model C-1X
Coagulometru portabil Cod 151120 Descriere Coagulometru automat destinat pentru testarea mostrelor preluate de la pacienti pentru determinarea factorilor de coagulare a sângelui. Parametrul Specificația Configurația portabil Teste APTT da FIB da PT da TT da Altele să se indice Calibrarea automată da Data management Display da Memorie internă da Imprimantă da	Coagulometru portabil Cod 151120 Descriere Coagulometru semi-automat destinat pentru testarea mostrelor preluate de la pacienti pentru determinarea factorilor de coagulare a sângelui. Parametrul Specificația Configurația portabil, 1 canal Teste APTT da FIB da PT da TT da Intrinsic, Extrinisic Factors AT, Proteina C, AutoD-Dimer Calibrarea automată da Data management Display 4.3”(480×272pixels)da Memorie internă da Imprimantă da

Digitally signed by Ceaicovschi Tudor
Date: 2022.09.15 12:46:06 EEST
Reason: MoldSign Signature
Location: Moldova

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CERTIFICATE

Certificate Number
PR 08 08 0022 003

Date of Issue
28 August 2008

Expiration Date
NONE

Test Report Number/s
E-0022-2619-00 MG
S-0022-2128-01 BT
S-0022-2128-02 BT

Product Description
Coagulometer

Page
1 of 1

Holder of Certificate :
Helena Laboratories (UK) ltd trading as
Helena Biosciences Europe
Queensway South, Team Valley Trading Estate, Gateshead, Tyne & Wear, NE11 9SD, United Kingdom

Manufacturer :
Helena Laboratories (UK) ltd trading as
Helena Biosciences Europe
Queensway South, Team Valley Trading Estate, Gateshead, Tyne & Wear, NE11 9SD, United Kingdom

Type/Model Name/s: Helena C-1, C-2, C-4

Directive/s: **2004/108/EC**
2006/95/EC

Standard/s:
EN 61326-1:2006
EN 61000-3-2:2000
EN 61000-3-2:2006
EN 61000-3-3:1995+A1:2001+A2:2005
EN 61010-1:2001 (2nd Edition)
EN 61010-2-101:2002 (1st Edition)

The certificate is issued after testing of the named product/s and/or audit of the technical documentation and confirms that the tested product complies with the essential protection requirements of the mentioned directives on a voluntary basis.

2008-08-28
Date

Signature

CE After preparation of the necessary technical documentation as well as the conformity declaration the required marking can be affixed to the product. Other relevant directives have to be observed. See also notes overleaf.

Zertifikat Certificado CERTIFICATE 011693 Approved

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Declaration of Conformity

for the Helena C-Series Instruments

Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 concerning In Vitro Diagnostic Medical Devices

The undersigned, under their sole responsibility, declares that the products described in this document meet the Council provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Helena C-Series Instruments
Legal Manufacturer: (Name on Label)	**Helena Biosciences Europe** Queensway South, Team Valley Trading Estate, Gateshead Tyne and Wear, NE11 0SD United Kingdom
SRN:	Not yet acquired.
Basic UDI-DI:	505601300C-SERIESWV
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Purpose:	The Helena C-Series, which consists of Helena C-1, Helena C-2 and Helena C-4 is a family of in-vitro diagnostic semi-automated coagulation analysers, for optical analysis of citrated plasma samples. The Helena C-Series instruments are to be used in conjunction with associated quantitative and qualitative Helena Biosciences Europe haemostasis reagents and applications. Designed for use by trained laboratory professionals in a clinical laboratory.
IVDR Classification:	Class A [Rule 5b]
Notified Body:	Not required
CE Certificate:	Not applicable for Class A.
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.
EU Authorised Representative SRN:	MT-AR-000000234
IVDR Assessment Route:	Issuing of the Declaration of Conformity in accordance with Article 17 after drawing up the technical documentation in Annexes II and III of the EU IVDR 2017/746.

EU Declaration of Conformity

Name Carol J Sandercock **Position** QA & Regulatory Affairs Associate Director/PRRC

Signed _____ **Date** _____ **Place** Gateshead, UK

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications (CS):

Standard/CS/Document Name	Description
2017/746	Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 concerning In Vitro Diagnostic Medical Devices
EN ISO 13485:2016+A11:2021	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2019+A11:2021	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2021	Medical devices. Symbols to be used with information to be supplied by the manufacturer - General requirements
EN ISO 20417:2021	Medical devices. Information to be supplied by the manufacturer
EN ISO 18113-1:2011	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 1: Terms, definitions and general requirements
EN 62366-1:2017	Medical Devices - Part 1: Application of Usability Engineering To Medical Devices
2014/30/EC	Directive 2014/30/EC of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility
EN 61326-1:2013	Electrical equipment for measurement, control and laboratory use-EMC requirements Part 1: General requirements
EN 55011: 2009 + A1:2010	Limits and methods of measurement of radio disturbance characteristics of industrial, scientific and medical (ISM) radiofrequency equipment.
2014/35/EU	Low Voltage Equipment Directive
EN 61010-1:2010+AMD1:2016	Safety requirements for electrical equipment for measurement, control, and laboratory use. General requirements
IEC 61010-2-101:2015	Safety requirements for electrical equipment for measurement, control and laboratory use. Particular requirements for in vitro diagnostic (IVD) medical equipment
IEC 61010-1:2010	Safety requirements for electrical equipment for measurement, control, and laboratory use. General requirements
(EU) 2015/863 amending Annex II to 2011/65/EU	Commission Directive 2015/863 amending Directive of the European Parliament and of the Council of 8 June 2011 on the

	restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS 3)
EN IEC 63000:2018	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

Appendix II – Product Listing/Schedule

Catalogue Number / UDI-DI	Device Description	EMDN Code
C-1X / 5056013023036	Helena C-1	W020202
C-2X / 5056013022985	Helena C-2	W020202
C-4X / 5056013022992	Helena C-4	W020202

Version History

Version	Compiled by	Date	Description
1	C Sandercock	05May2022	Initial version

Technical Specifications

	Helena C-1	Helena C-2	Helena C-4
Optical measurement channels	1	2	4
Optical wavelength	405 nM (UV)		
Automatic light level adjustment	Y		
Reagent/optic warming	Y		
Cuvette pre-warm	10×	20×	20×
Reagent pre-warm, 24mm	1×	1×	1×
Reagent pre-warm, 22mm	2×	2×	2×
Microtubes pre-warm	2×	2×	2×
Reagent stirrer	N	1×	1×
Cuvettes	Single, 75 µL; activated via www.c-series.com or TECAM software		
Auto-start	Yes, on reagent addition		
Samples			
Patient ID	No	Y	Y
Double determination	No	Up to 200 results	Up to 200 results
Whole-blood testing	N		
Assays			
Dual reagent lots	No	Y	Y
Global clotting assays	PT, aPTT, Fibrinogen, TT		
Special clotting assays	Intrinsic and Extrinisic Factors		
Chromogenic assays	AT, Protein C		
Latex-enhanced assays	Auto D-Dimer (Blue)		
Hardware Specifications			
Display	4.3” (480×272 pixels) with capacitive touchscreen control		
Multi-language	Y		
Printer	Optional external printer (RS232)		
Barcode scanner	Optional external 1D barcode scanner (RS232)		
LIMS connectivity	Yes, via TECAM software		
Dimensions	225 mm × 150 mm × 90 mm (L × W × H)		
Power supply	Input 110–240V at 50–60 Hz; output 5V, 3.3A		

Quality and reliability from the reagent experts.

helena
Biosciences Europe

C-Series is the ideal platform to use Helena's reliable, market-tested portfolio of reagents. Our flexible range of kit formats provide unbeatable quality and value regardless of throughput.

Routine Assays

- PT
- aPTT
- Clauss Fibrinogen
- Thrombin Time

Factor Deficient Plasmas (Immunodepleted)

- Factor II Deficient Plasma
- Factor V Deficient Plasma
- Factor VII Deficient Plasma
- Factor VIII Deficient Plasma
- Factor IX Deficient Plasma
- Factor X Deficient Plasma
- Factor XI Deficient Plasma
- Factor XII Deficient Plasma

Specialist Assays

- Auto Blue D-Dimer 400
- DRVVT Screen
- DRVVT Confirm

Chromogenic Assays

- Antithrombin Xa (Chromogenic)
- Protein C (Chromogenic)

Calibrators and Controls

- Calibration Plasmas
- Routine Controls
- Speciality Assayed Controls

Contact Helena for more information

Email sales@helena-biosciences.com

Training certificate

helena
Biosciences Europe

This is to certify that

Sergeu Sorokovice

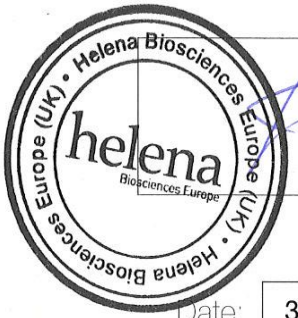
from

IM Global Biomarketing Group

has received training on the following:

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

Signed:



Date: 31st October - 4th November 2011

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