Anexa 8 la Formularul Specificatie Tehnica

Modelul: Helena C-4 (cod cat. C-4X) ; Producător: Helena Biosciene. Tara: Marea Britanie.

Specificația tehnică deplină solicitată	Specificația tehnică deplină propusă, model **Helena C-4** (cod cat. C-4X)
Coagulometru semi-automat Descriere Coagulometru semiautomat destinat pentru testarea mostrelor preluate de la pacienţi pentru determinarea factorilor de coagulare a sîngelui. Parametrul Specificația Configurația Capacitatea sistemului 4 probe simultan Tip probă plasmă Teste APTT FIB PT TT Data management Display LCD sau LED Imprimantă Interfață PC Interfață LIS Cititor bar cod	Coagulometru semi-automat Descriere Coagulometru semiautomat destinat pentru testarea mostrelor preluate de la pacienţi pentru determinarea factorilor de coagulare a sîngelui. Parametrul Specificația Configurația Capacitatea sistemului 4 probe simultan Tip probă plasmă PT, aPTT, Fibrinogen, TT Intrinsic si Extrinisic Factors AT, Protein C Auto D-Dimer (Blue) Data management Display touchscreen control Imprimantă Interfață PC Interfață LIS Cititor bar cod

Digitally signed by Ceaicovschi Tudor
Date: 2024.04.19 17:54:42 EEST
Reason: MoldSign Signature
Location: Moldova

helena
Biosciences Europe

C-Series

1, 2 and 4-channel Coagulometers

Introductory Offers

Only until 31st March 2020

Speed and flexibility in a compact, friendly format.

Key features

- **Flexible platform with 1, 2 or 4 channels**

  High-performance optical analysis with no requirement for mechanical stirring

- **Sensitive detection with small sample volumes**

  High-resolution optical measurement, even with only 75µL sample and reagent volume

- **User-friendly operation**

  Brand-new touchscreen workflow allows simple programming and automatic start

- **Automatic optical adjustment**

  Ensures reliable results across all channels when sample quality varies

- **Powerful connectivity**

  Patient and sample ID tracking with optional external bar code scanner

- **High quality construction**

  Tried-and-tested analytical platform, designed and manufactured in the EU

Learn more at www.c-series.com

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		

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Введите текст для поиска...

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data
						Helena			
DM000392673	ANALIZATOR SEMI-AUTOMAT PENTRU COAGULARE		HELENA C-2	C-2X	Marea Britanie	HELENA BIOSCIENCES EUROPE	GBG-MLD S.R.L.	Rg04-000280	28-11-2022
DM000392676	REAGENT		IMIDAZOLE BUFFER	5375R	Marea Britanie	HELENA BIOSCIENCES EUROPE	GBG-MLD S.R.L.	Rg04-000280	28-11-2022
DM000392678	REAGENT		CALCIUM CHLORIDE	5386	Marea Britanie	HELENA BIOSCIENCES EUROPE	GBG-MLD S.R.L.	Rg04-000280	28-11-2022
DM000392674	ANALIZATOR SEMI-AUTOMAT PENTRU COAGULARE		HELENA C-4	C-4X	Marea Britanie	HELENA BIOSCIENCES EUROPE	GBG-MLD S.R.L.	Rg04-000280	28-11-2022
DM000392672	ANALIZATOR SEMI-AUTOMAT PENTRU COAGULARE		HELENA C-1	C-1X	Marea Britanie	HELENA BIOSCIENCES EUROPE	GBG-MLD S.R.L.	Rg04-000280	28-11-2022

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