AESKU.DIAGNOSTICS
THE DIAGNOSTIC TOOL THAT WORKS

Declaration of Conformity

According to IVDR (In Vitro Diagnostic Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017):

AESKU.Diagnostics GmbH & Co. KG
Mikroforum Ring 2
55234 Wendelsheim
Germany
SRN: tbd

We declare under our sole responsibility that the below mentioned in vitro diagnostic medical devices comply with all requirements of Regulation (EU) 2017/746 and the relevant harmonized standards. The conformity of the Regulation has been carried out according to Annex IV.

Product name with registered trademark: HELMED® Automated IFA Processor

Intended Purpose:

The **HELMED® Automated IFA** Processor is an automated system for the processing of indirect immunofluorescence assays (IIFA) under controlled conditions in terms of relative humidity and temperature; intended as an aid for in-vitro diagnosis of autoimmune and infectious diseases. The manual evaluation of processed assays should be performed by trained healthcare professionals. The device is intended for professional use only.

Cells/tissue coated microscopy slides are used as a substrate for the qualitative and/or semi-quantitative determination of antibodies in human serum by automated processing of indirect immunofluorescence assays (IIFA) with the **HELMED® Automated IFA Processor**.

The **Humidity Temperature Control (HTC) Kit** as an optional accessory enables the system to adjust and maintain the internal parameters in terms of humidity and temperature. The **Humidity Temperature Control (HTC) Kit (REF.HTC-1001)** is intended to be used with **REF.IOS-1000 (HELIOS®) or REF.HEL-1000 (HELMED®)**.

The **HTC** function offering a new range of infectious serology substrates for our automated IFAs, including markers for e.g., EBV, HSV, Adenovirus and Borrelia for automated determination of IgM antibodies by processing immunofluorescence assays with higher incubation temperature (35-37°C/ 95-98,6°F) in an internal adjusted environment. The device is intended for professional use only.

The **HELMED® IFA BLOT Upgrade Kit** is an extension module for the **HELMED®** IFA Processor. It enables processing of **AESKUBLOTS®** assays produced by AESKU.Diagnostics GmbH & Co.KG. To utilize **AESKUBLOTS®** kit components and reagents, the system requires the blot carousel (tray holder ring), a cam disc, two reagent racks and a sample rack in combination with the software provided. The device is intended for professional use only.

To use the **HELMED® BLOT Software**, a complete **HELMED® IFA Processor** is required. This consists of the following components: **HELMED®** IFA Processor, PC (not included) and printer (not included).

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Basic UDI-DI: 42502895HELMEDFH

REF-Number(s): See table 1 below

Classification according to Annex VIII of Regulation (EU) 2017/746: Class A

Valid until: 25.05.2027

Table 1: Reference numbers included in the present Declaration of Conformity

Reference number	Product name	UDI-DI
REF.HEL-1000	HELMED® Automated IFA Processor	04250289512565
REF.HTC-1001	Humidity Temperature Control (HTC) Kit	04250289512640
REF.HEL-8002	HELMED® IFA BLOT Upgrade Kit	04250289512657

Wendelsheim, 25.05.2022

Place and date of issuing the declaration

Dr. Torsten Matthias
CEO
AESKU.Diagnostics GmbH & Co. KG