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: HELIOS® Automated IFA System

Intended Purpose:

The **HELIOS® Automated IFA System** is an automated laboratory device performing and analyzing the indirect immunofluorescence assays (IIFA) under controlled conditions in terms of humidity and temperature for in-vitro determination of antibodies in human serum related to autoimmune and infectious diseases. The device is an aid to diagnosis. All suggested results obtained by HELIOS® Automated IFA System in conjunction with other clinical and laboratory findings must be confirmed 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 and analyzing of indirect immunofluorescence assays (IIFA) with the **HELIOS® Automated IFA System.**

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.

Basic UDI-DI: 42502895HELIOSGR

REF-Number(s): See table 1 below

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

Valid until: 25.05.2027

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

Reference number	Product name	UDI-DI
REF.IOS-1000	HELIOS® Automated IFA System	04250289512541
REF.HTC-1001	Humidity Temperature Control (HTC) Kit	04250289512640

Wendelsheim, 25.05.2022

Place and date of issuing the declaration

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