EU DECLARATION OF CONFORMITY

Manufacturer:

DiaSys Diagnostic Systems GmbH
Alte Strasse 9
65558 Holzheim
Germany

SRN: DE-MF-000025417

Product name	Cat. No.	Basic UDI-DI	Intended use	Risk class
InnovaStar®	970 100	4051839970100YE	Benchtop random access clinical chemistry analyzer for in vitro diagnostic use. For professional use only.	A
System Solution InnovaStar	970 115	4051839970115YT	Wash solution for clinical chemistry analyzer	A
DiaCapil Sample Cups InnovaStar® 10/500	970 113 970 114	04051839970113YP 04051839970114YR	Pre filled sample cups for sample dilution	A

We, as the manufacturer of the devices take sole responsibility for and hereby declare that the mentioned products listed above meet the provisions of the Regulation (EU) 2017/746 on in-vitro diagnostic medical devices.

Conformity route: Annex IX Quality Management System for class A devices and technical documentation according Annex II and Annex III.

Additional applicable directives: Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS).

DiaSys Diagnostic Systems GmbH
Holzheim, 2023-10-17
Dr. Jan Gorka
Managing Director + CEO

CE