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
respons®920	960 100	4051839960100Y3	Benchtop random access clinical chemistry analyzer for in vitro diagnostic use. For professional use only.	A
respons®920 complete	960 920	4051839960100Y3	Benchtop random access clinical chemistry analyzer for in vitro diagnostic use. For professional use only.	A
respons®920 (ISE)	960 200	4051839960200Y8	Benchtop random access clinical chemistry analyzer with integrated ion selective electrodes unit (ISE) for in vitro diagnostic use. For professional use only.	A
respons®920 complete (ISE)	960 921	4051839960200Y8	Benchtop random access clinical chemistry analyzer with integrated ion selective electrodes unit (ISE) for in vitro diagnostic use. For professional use only.	A
Cleaner A	186109910923	04051839186109C	Wash solution for clinical chemistry analyzer	A
Cleaner B	186509910923	04051839186509Q	Wash solution for clinical chemistry analyzer	A
Cleaner respons 920/940	188309910885	04051839188309U	Wash solution for clinical chemistry analyzer	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, 2023-01-23
Dr Jan Gorka
Managing Director + CEO

CE