CE

EU Declaration of Conformity

GEMINI

Compact Microplate Processor

Product Code/ Article Number:	10041566
Basic UDI-DI:	42606786862804M
Classification:	☒ A ☐ B ☐ C ☐ D Rule 5, Annex VIII, IVD Regulation
Conformity Route	☐ Annex IX Technical documentation Examination ☐ ANNEX IX Full Quality System ☐ ANNEX XI Production Quality System ☒ ANNEX I + II + III
Legal manufacturer:	**STRATEC SE** **Gewerbestraße 37** **75217 Birkenfeld** **Germany**
SRN:	DE-MF-000007261

We, as the manufacturer of the device specified above, declare under our sole responsibility that the product meets all applicable requirements of the following directives:

Legal Requirement	Title
IVD Regulation (IVDR) (EU) 2017/746	REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU
RoHS Directive 2011/65/EU	DIRECTIVE 2011/65/EU 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

Conformity assessment was successfully conducted according to the stipulations of the respective directive.

The application of the Gemini Instrument for in vitro diagnostic purposes requires a separate conformity assessment according to Regulation (EU) 2017/746 for the full system into which it will be incorporated and / or is used in combination with (e.g. assay).

We confirm that the Gemini Instrument does not contain the hazardous substances specified in Directive 2011/65/EU in concentrations exceeding the indicated threshold values.

This Declaration of Conformity is valid for the instrument´s configuration and the regulatory requirements effectual at the date the Declaration was issued. Changes affecting the instrument, and / or the applicable regulations trigger a review of the conformity assessment the Declaration is based on, and the issuance of a new version of the document.

Date: 2022-05-16

Place: Birkenfeld

Signature:

STRATEC SE
Gewerbestr. 37
75217 Birkenfeld
www.stratec.com

Dr. Volker Schwaab
Head of Corporate Quality Management & Regulatory Affairs
STRATEC SE