CE

EU Declaration of Conformity

GEMINI

Compact Microplate Processor

Device Code/ Article Number:	10041566
Basic UDI-DI:	42606786862804M
Classification:	☒ A ☐ B ☐ C ☐ D Rule 5, per *Regulation (EU) 2017/746, Annex VIII*
Conformity Assessment Route	☐ Annex IX Assessment of Technical Documentation ☐ Annex IX Assessment based on a Quality Management System ☐ Annex XI Assessment based on Production Quality Assurance ☒ Annex I, II, III
Legal Manufacturer:	STRATEC SE Gewerbestraße 37 75217 Birkenfeld Germany
Single Registration Number (*SRN*):	DE-MF-000007261

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

Legal Requirement	Title
Regulation (EU) 2017/746 (IVDR)	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
Directive 2011/65/EU RoHS	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 has been successfully conducted according to the stipulations of the respective legislation.

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).

This Declaration of Conformity is valid for the *in vitro* diagnostic medical device´s configuration and the regulatory requirements effectual at the date the Declaration was issued. Changes affecting the *in vitro* diagnostic medical device 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:	2024-03-18
Place:	Birkenfeld
Signature:	

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