CE

EU Declaration of Conformity

KLEEYA® TRIGGER SOLUTIONS PACK

solutions for the chemiluminescence signal generation in the fully automated chemiluminescence immunoassay analyzer KleeYa

Product Code/ Article Number:	226491-TRP
Basic UDI-DI:	5999860094KTSTJ
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:	**Diatron MI Plc.** **H-1097 Táblás u. 39, Budapest, Hungary**
SRN:	HU-MF-000020416

We, as the manufacturer of the device specified above, declare under our sole responsibility that the product meets all applicable requirements of the following regulation and directive(s):

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

Conformity assessment was successfully conducted according to the stipulations of the respective regulation / directive(s).

The application of the Trigger solutions 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 device's configuration and the regulatory requirements effectual at the date the Declaration was issued. Changes affecting the 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.

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Date:	2024-01-17
Place:	Budapest
Signature:	

diatron

Péter Zsóka
Director of finance