CE

EU Declaration of Conformity

5x TBS Wash Buffer

wash buffer for the chemiluminescence reaction in the fully automated chemiluminescence immunoassay analyzer KleeYa

Product Code/ Article Number:	TWB56
Basic UDI-DI:	5999860094KWSTT
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 Wash Buffer 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.

Date:	2024-10-17
Place:	Budapest
Signature:	

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