

## EU Declaration of Conformity

according to the European In-Vitro-Diagnostics  
Regulation (EU) 2017/746

We,

**Waldeck GmbH & Co.KG**  
**Havixbecker Str. 62**  
**48161 Münster**  
**Germany**

Single registration number (SRN): *requested*

hereby declare under our sole responsibility that the products listed in Appendix 1 of the following product group:

- Stain solutions / (Histology/Cytology)

comply with the conformity assessment procedure set out in Annex IV of Regulation (EU) 2017/746 and that all applicable essential safety and performance requirements set out in Annex I are met. And the procedures as specified in Annex II and Annex III of the same Regulation have been followed. The classification of the products listed above is in accordance with Annex VIII of the above-mentioned Regulation.

We declare that the products comply with this Regulation, as well as with other relevant Union legislation, if any.

This declaration is valid for products placed on the market as of the date of issue.

This document is valid until 31.12.2025.

Münster, 29.12.2022



Dr. Schröder  
Laboratory Manager  
(legally binding signature)

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Regulation (EU) 2017/746

### Appendix 1:

**Product group:** Stain solutions / (Histology/Cytology)

**EDMA Code:** 13-07-01-08-00

Produktname	Article number	Class	Rule
Methylene Blue, alkaline	1A-158.00010	A	5
	1A-158.00025		
	1A-158.00100		
	1A-158.00250		