



# EU Declaration of Conformity

## for Dade Owren's Veronal Buffer

Siemens Healthcare Diagnostics Products GmbH hereby declares conformity to 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 for the following In Vitro Diagnostic Device:

### Product Name

Dade Owren's Veronal Buffer

### Intended Purpose Statement of Device

Dade Owren's Veronal Buffer is a dilution buffer for coagulation testing.

Catalogue Number (REF)	Siemens Material Number (SMN)	Package Size / Description
B4234-25	10445724	10 x 15 mL

### Basic UDI-DI (Basic Unique Device Identification)

0405686900864W5

### Risk classification according to the rules of Annex VIII REGULATION (EU) 2017/746

Class A

### Manufacturer and address of registered place of business

Manufacturer	Siemens Healthcare Diagnostics Products GmbH
Single Registration Number	DE-MF-000005039
Address	Emil-von-Behring-Str. 76 35041 Marburg Germany

### Notified Body

Name	N/A
Identification Number	N/A
Address	N/A

Conformity Assessment Procedure	Article 48 (10)
---------------------------------	-----------------



# EU Declaration of Conformity

## for Dade Owren's Veronal Buffer

**Notified Body Certificate Number**

N/A

**Common Specifications the product conforms with**

Identifier Title of Document

N/A

N/A

This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Products GmbH according to REGULATION (EU) 2017/746 for the following In Vitro Diagnostic Device and any other Union legislation as stated in the Conformity with Standards and supersedes any declaration issued previously for the same product.

**Signature:**

Electronically signed by:  
Andreas Wiegand  
Reason: I am approving  
this document  
Date: Sep 30, 2021  
09:22 GMT+2

**Email:** ANDREAS.WIEGAND@SIEMENS-HEALTHINEERS.COM

Andreas Wiegand  
Senior Director Regulatory Affairs  
Siemens Healthcare Diagnostics Product GmbH  
Marburg, Germany

**Date:**  
Sep 30, 2021