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SIEMENS Healthineers

EU Declaration of Conformity

for Multifibren U

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

Multifibren U

Intended Purpose Statement of Device

Multifibren U is an in vitro diagnostic reagent for the quantitative determination of fibrinogen as an aid to diagnosis of congenital or acquired fibrinogen deficiency or dysfunction in patients with bleeding disorders or at risk for fibrinogen deficiency in human sodium citrated plasma by means of automated and manual coagulometric methods.
Fibrinogen determination by Multifibren U is standardized against the reference methods by Ratnoff-Menzie and Kjeldahl.
In addition, Multifibren U reagent can be used as an aid in diagnosis and monitoring of fibrinogen consumption in patients at risk or with signs of disseminated intravascular coagulopathy (DIC).

Catalogue Number (REF)	Siemens Material Number (SMN)	Package Size / Description
OWZG19	10446689	10 x 2 mL
OWZG23	10446691	10 x 5 mL

Basic UDI-DI (Basic Unique Device Identification)

0405686900877WE

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

Class C

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	TÜV Rheinland LGA Products GmbH
Identification Number	0197
Address	Tillystr. 2 90431 Nürnberg Germany
Conformity Assessment Procedure	Annex IX

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Notified Body Certificate Number

HX 1512506-1

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: A Wiegand

Electronically signed by:
Andreas Wiegand
Reason: I am approving this document
Date: Sep 30, 2021 09:20 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

Digitally signed by Dicusar Larisa
Date: 2023.12.04 16:50:13 EET
Reason: MoldSign Signature
Location: Moldova