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SIEMENS Healthineers

EU Declaration of Conformity

for Standard Human Plasma

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

Standard Human Plasma

Intended Purpose Statement of Device

Standard Human Plasma is used for the calibration of the following tests:
Prothrombin time (PT); Fibrinogen (Clauss method); Coagulation factors: FII, FV, FVII, FVIII, FIX, FX, FXI, FXII, FXIII and vWF; Inhibitors: Antithrombin III, protein C, protein S, α2-antiplasmin, C1-Inhibitor; Plasminogen. Furthermore, Standard Human Plasma shall be used as sample dilution medium for selected assays, if indicated in the application sheets for these assays. In addition, the stated sensitivity values for ProC reagents are provided for calculating the normalized ratio for ProC Global and ProC Global/FV.

Catalogue Number (REF)	Siemens Material Number (SMN)	Package Size / Description
ORKL17	10446238	10 x 1.0 mL

Basic UDI-DI (Basic Unique Device Identification)

0405686900193V9

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: Aug 3, 2021 15:33 GMT+2

Email: ANDREAS.WIEGAND@SIEMENS-HEALTHINEERS.COM

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

Date:
2021-08-03

Digitally signed by Dicusar Larisa
Date: 2023.12.04 16:50:42 EET
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