CE

SIEMENS Healthineers

EU Declaration of Conformity

for Thromborel S

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

Thromborel S

Intended Purpose Statement of Device

Thromborel S is an in vitro diagnostic reagent for the quantitative determination of prothrombin time (PT) as an aid to diagnosis, screening for hemostasis disorders and monitoring of oral anticoagulation therapy with vitamin K antagonists in human sodium citrated plasma by means of automated, semiautomated and/or manual coagulometric methods. For monitoring vitamin K antagonist anticoagulation therapy PT is reported in WHO-standardized INR (International Normalized Ratio).

Catalogue Number (REF)	Siemens Material Number (SMN)	Package Size / Description
OUHP29	10446442	10 x 4mL
OUHP49	10446445	10 x 10mL
10484202	10484202	10 x 10mL (RiLiBÄK)

Basic UDI-DI (Basic Unique Device Identification)

0405686900194VB

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

Digitally signed by Marinescu Traian alin
Date: 2025.03.28 13:39:58 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

CE

SIEMENS Healthineers

EU Declaration of Conformity

for Thromborel S

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 12:40 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

CE

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

CE

SIEMENS Healthineers

EU Declaration of Conformity

for Multifibren U

Notified Body Certificate Number

HX 1512506-1

Common Specifications the product conforms with

Identifier	Title of Document
N/A	N/A

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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

CE

SIEMENS Healthineers

EU Declaration of Conformity

for Kaolin Suspension

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

Kaolin Suspension

Intended Purpose Statement of Device

Kaolin Suspension is used as Supplementary Reagent for the Fibrintimer (BFT II Analyzer).

Catalogue Number (REF)	Siemens Material Number (SMN)	Package Size / Description
OQAB45	10446033	1 x 50 mL

Basic UDI-DI (Basic Unique Device Identification)

0405686900874W8

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)

CE

SIEMENS Healthineers

EU Declaration of Conformity

for Kaolin Suspension

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: A. Wiegand

Electronically signed by:
Andreas Wiegand
Reason: I am approving this document
Date: Sep 30, 2021 09:18 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

CE

SIEMENS Healthineers

EU Declaration of Conformity

for PT-Multi Calibrator

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

PT-Multi Calibrator

Intended Purpose Statement of Device

PT-Multi Calibrator is a calibrator set for the direct calibration of the prothrombin time (PT) by Dade Innovin and Thromborel S in INR and % of Norm. For the determination of a local ISI value.

Catalogue Number (REF)	Siemens Material Number (SMN)	Package Size / Description
OPAT03	10445969	1 x 1 mL, PT-Multi Calibrator Level 1 1 x 1 mL, PT-Multi Calibrator Level 2 1 x 1 mL, PT-Multi Calibrator Level 3 1 x 1 mL, PT-Multi Calibrator Level 4 1 x 1 mL, PT-Multi Calibrator Level 5 1 x 1 mL, PT-Multi Calibrator Level 6

Basic UDI-DI (Basic Unique Device Identification)

0405686900192V7

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

CE

SIEMENS Healthineers

EU Declaration of Conformity

for PT-Multi Calibrator

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 15:29 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

CE

SIEMENS Healthineers

EU Declaration of Conformity

for Control Plasma N

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

Control Plasma N

Intended Purpose Statement of Device

Control Plasma N is an assayed control used for the assessment of precision and analytical deviation of the following analytes in the normal range:

1. Prothrombin time (PT)
2. Activated partial thromboplastin time (APTT)
3. Thrombin time (TT)
4. Batroxobin time
5. Fibrinogen
6. Coagulation factors II, V, VII, VIII, IX, X, XI, XII, XIII and vWF
7. Inhibitors: Antithrombin III, protein C, protein S, α2-antiplasmin, C1-Inhibitor
8. Plasminogen
9. ProC line analytes
10. Lupus anticoagulants

The assigned values were determined at Siemens Healthcare Diagnostics Products GmbH using Siemens Healthineers reagents on mechanical and photo-optical coagulation systems.

Catalogue Number (REF)	Siemens Material Number (SMN)	Package Size / Description
ORKE41	10446234	10 x 1mL
10484201	10484201	10 x 1mL (RiLiBÄK)

Basic UDI-DI (Basic Unique Device Identification)

0405686900162UW

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

CE

SIEMENS Healthineers

EU Declaration of Conformity

for Control Plasma N

Address	Tillystr. 2 90431 Nürnberg Germany
Conformity Assessment Procedure	Annex IX

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: S. Matern

Electronically signed by:
Sanja Matern
Reason: I am approving this document
Date: Aug 9, 2021 19:11 GMT+2

Email: sanja.matern@siemens-healthineers.com

Dr. Sanja Matern	Date
Regulatory Affairs Manager / Head of Product Group	2021-08-09
Siemens Healthcare Diagnostics Product GmbH	[YYYY-MM-DD]
Marburg, Germany	

CE

SIEMENS Healthineers

EU Declaration of Conformity

for Control Plasma P

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

Control Plasma P

Intended Purpose Statement of Device

Control Plasma P is an assayed control used for the assessment of precision and analytical deviation of the following analytes in the pathological range:

1. Prothrombin time (PT)
2. Activated partial thromboplastin time (APTT)
3. Fibrinogen (Clauss method)
4. Coagulation factors II, V, VII, VIII, IX, X, XI, XII, XIII and vWF
5. Inhibitors: Antithrombin III, protein C, protein S, α2-antiplasmin, C1-Inhibitor
6. Plasminogen
7. Thrombin time[a]

The values were determined using Siemens Healthineers reagents on mechanical and photo-optical coagulation analyzers.

[a] Availability of application and assigned value may vary by country

Catalogue Number (REF)	Siemens Material Number (SMN)	Package Size / Description
OUPZ17	10446471	10 x 1mL
10484203	10484203	10 x 1mL (RiLiBÄK)

Basic UDI-DI (Basic Unique Device Identification)

0405686900163UY

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

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SIEMENS Healthineers

EU Declaration of Conformity

for Control Plasma P

Conformity Assessment Procedure Annex IX

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: S. Matern

Electronically signed by: Sanja Matern Reason: I am approving this document Date: Aug 9, 2021 19:34 GMT+2

Email: sanja.matern@siemens-healthineers.com

Dr. Sanja Matern	Date
Regulatory Affairs Manager / Head of Product Group	2021-08-09
Siemens Healthcare Diagnostics Product GmbH	[YYYY-MM-DD]
Marburg, Germany	