



## EU Declaration of Conformity

as per Annex IV of the Regulation EU 2017/746 on in-vitro diagnostic medical devices

**Manufacturer:** Roche Diagnostics GmbH  
**Address:** Sandhofer Strasse 116  
68305 Mannheim  
Germany  
**Single Registration Number:** DE-MF-000006260

Roche Diagnostics GmbH declares, under the sole responsibility, that the product/the product line

Product Name	Cat. No. / REF	Basic UDI-DI
Prostaglandin E1 Reagent	08847525190	7613336010189X

### Intended Use:

Reagent for the quantitative in vitro determination of platelet function triggered by adenosine diphosphate and Prostaglandin E1 Reagent (in conjunction with reagent ADPtest). The reagent is intended for use in platelet function testing with whole blood samples on the Multiplate analyzer. For the assessment of ADPtest HS (high sensitivity).

**Risk Class:**  A  B  C  D

### **Conformity Route:**

- Self-Declaration of Conformity (Class A)
- Self-Declaration of Conformity after Notified Body involvement for sterile manufacturing conditions acc. Art. 48 (10) (Class A sterile)
- Technical Documentation Assessment Class B/C – Annex IX
- Technical Documentation Assessment Class D – Annex IX
- Technical Documentation Assessment Class B/C/D for Self-Testing – Annex IX
- Technical Documentation Assessment Class B/C/D for Near-Patient Testing – Annex IX
- Technical Documentation Assessment Class C/D for Companion Diagnostics

### **Certificates:**

- EU QM Certificate No.: V13 010283 0732
- EU Technical Documentation Assessment Certificate No. (Class D, Near-Patient Testing, Self-Testing and Companion Diagnostics):

### **Other:**

- Common Specifications:

Roche Diagnostics GmbH; Sandhofer Straße 116; D-68305 Mannheim; Telefon +49-621-759-0; Telefax +49-621-759-2890

Sitz der Gesellschaft: Mannheim - Registergericht: AG Mannheim HRB 3962 - Geschäftsführung: Dr. Claudia Fleischer; Dr. Virginia Bastian

Aufsichtsratsvorsitzender: Dr. Thomas Schinecker



**Notified Body (NB) Name:** TÜV Süd Product Service GmbH

**NB Address:** Ridlerstraße 65  
80339 Munich  
Germany


**NB Ident. No.:** 0123

*to which this declaration relates fulfils the requirements of Regulation EU 2017/746 on in-vitro diagnostic medical devices.*

Mannheim,

Roche Diagnostics GmbH

*ppa./on behalf of the company*

Signed by:  



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Dr. Nicole Zein  
Site Quality Head / Network Lead, Mannheim

Mannheim,

Roche Diagnostics GmbH

*ppa./on behalf of the company*

Signed by:  


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Dr. Stefan Scheib  
Global Head of Regulatory Affairs, Core Lab

*Contact address:* Roche Diagnostics GmbH  
Global Regulatory Affairs  
Sandhofer Strasse 116  
68305 Mannheim  
Germany