



Product Service

CERTIFICATE

No.

Holder of Certificate:

Facility(ies):

Certification Mark:



Scope of Certificate:

Design and Development,
Production and Distribution of
In-vitro Diagnostic Test Kits
based on Latex Particle-enhanced
Turbidimetric Immunoassay and
Quantum Dot Immunofluorescence
Assay, Dry-type Fluorescence
Immunity Analyzer

Applied
Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.:

Valid from:

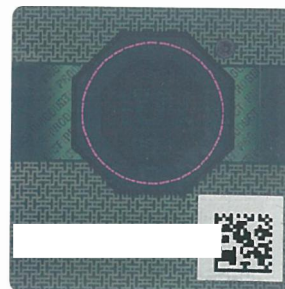
2018-05-09

Valid until:

2021-05-08

Date, 2018-05-09

Stefan Preiß



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