

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization
Sysmex Partec GmbH
Am Flugplatz 13
02828 Görlitz
Deutschland

has established and applies a quality management system for medical devices
for the following scope:

**Design and development, production, distribution and service
of instruments, accessories, reagents, consumables and
applications for cell and particle analysis
(see attachment for additional sites included)**

Proof has been furnished that the requirements specified in

EN ISO 13485:2012
EN ISO 13485:2012/AC:2012



are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2017-08-15
Certificate Registration No.: SX 60121809 0001
An audit was performed. Report No.: 21210632 008
This Certificate is valid until: 2019-03-30

Certification Body



Date 2017-07-28



Dipl.-Ing. I. Munkler

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60121809 0001
Report No.: 21210632 008

Organization: **Sysmex Partec GmbH**
Am Flugplatz 13
02828 Görlitz
Deutschland

Scope:

Sites included:

Sysmex Partec GmbH
Wilhelmsplatz 11
02826 Görlitz, Germany

Activities:
Management, human resources

Sysmex Partec GmbH
Otto-Hahn-Straße 32
48161 Münster, Germany

Activities:
Design and development, production, final inspection
and service

Certification Body



Date: 2017-07-28



Dipl.-Ing. I. Munkler

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60121809 0001
Report No.: 21210632 008

Organization: **Sysmex Partec GmbH**
Am Flugplatz 13
02828 Görlitz
Deutschland

Scope:

Sites included:

Sysmex Partec GmbH
Arndtstraße 11 a-b
02826 Görlitz, Germany

Activities:

Design and development, production, service,
final inspection, quality management and regulatory affairs

Sysmex Partec GmbH
Weißenfelser Str. 67
04229 Leipzig, Germany

Activities:

Design and development of hardware and embedded software

Certification Body



Date: 2017-07-28



Dipl.-Ing. I. Munkler