

## Certificate

## Quality Management System EN ISO 13485:2016

Registration No.:

SX 1743284-1

Organization:

Sysmex Partec GmbH

Arndtstr. 11 a-b 02826 Görlitz Germany

Scope:

Design and development, manufacture, distribution and service of

instruments, accessories, reagents, consumables and applications for cell

and particle analysis

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.

Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality

management system is subject to yearly surveillance.

Report No.:

3314728-90

Effective date:

2020-11-30

Expiry date:

2023-08-14

Issue date:

2020-11-30



Dipl.-Ing. (FH) D. Wiedemuth TÜV Rheinland LGA Products GmbH Tillystraße 2 · 90431 Nürnberg · Germany

TÜVRheinlar



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Registration No.:

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Sysmex Partec GmbH

Arndtstr. 11 a-b 02826 Görlitz Germany

The scope of certification also covers the following:

No. Facility Scope

/01 Sysmex Partec GmbH

Arndtstr. 11 a-b 02826 Görlitz Germany Design and development, manufacture, distribution and Management

/02 Sysmex Partec GmbH

Am Flugplatz 13 02828 Görlitz Germany Manufacture of mechanical parts

/03 Sysmex Partec GmbH

Otto-Hahn-Str. 32 48161 Münster Germany Design and development, installation and

service

/04 Sysmex Partec GmbH

Weißenfelser Str. 67

04229 Leipzig Germany Design and development

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DAKKS

Deutsche
Akkreditierungssteile
D-ZM-14169-01-02

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