

# Certificate

## Quality Management System EN ISO 13485:2016


Registration No. SX 1743284-1  
Certificate Holder Sysmex Partec GmbH  
Arndtstr. 11 a-b  
02826 Görlitz  
Germany

Scope Design and development, manufacture, distribution, installation and service of in-vitro diagnostic instruments, in-vitro diagnostic 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. 1133792-40  
Effective date 2023-08-15  
Expiry date 2026-08-14  
Issue date 2023-07-18  
Replaces certificate SX 1743284-1 issued 2021-10-11

This certificate can be validated on <https://www.certipedia.com>

  
M.Sc. Irene Carraretto  
TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany

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The scope of certification also covers the following sites:

No.	Facility	Scope
/01	c/o Sysmex Partec GmbH Arndtstr. 11 a-b 02826 Görlitz Germany	Design and development, manufacture, distribution and administration
/02	c/o Sysmex Partec GmbH Arndtstr. 11 02826 Görlitz Germany	Manufacture of mechanical parts
/03	c/o Sysmex Partec GmbH Otto-Hahn-Str. 32 48161 Münster Germany	Design and development, installation and service
/04	c/o Sysmex Partec GmbH Weißenseker Str. 67 04229 Leipzig Germany	Design and development

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*Irene Carraretto*

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TÜV Rheinland LGA Products GmbH  
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