

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

STAT DX LIFE S.L.
Baldri Reixac 4
08028 Barcelona
Spain

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

Details see attachment

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

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

Effective Date: 2018-12-20
Certificate Registration No.: SX 60135215 0001
An audit was performed. Report No.: 60170406 002
This Certificate is valid until: 2021-12-19

Certification Body



Date 2018-12-20



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 60135215 0001
Report No.: 60170406 002

Organization: STAT DX LIFE S.L.
Baldiri Reixac 4
08028 Barcelona
Spain

Scope:

Design and development, manufacture, service, installation and distribution of molecular diagnostic systems, including instruments, reagents and software used in the field of infectious diseases.

Design and development of immunoassay systems, including instruments, reagents and software used in the field of infectious diseases.

Certification Body



Date: 2018-12-20


Dipl.-Ing. Sven Hoffmann

