

# Certificate

The Certification Body of  
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**GENEXO Sp. z o.o.**  
**ul. Gen. Zajaczka 26**  
**01-510 Warszawa**  
**Poland**

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

**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: 2018-09-05  
Certificate Registration No.: SX 60128138 0001  
An audit was performed. Report No.: 26300167 007  
This Certificate is valid until: 2021-01-31

Certification Body



Date 2018-09-05

*Maciej Sciera*  
Maciej Sciera



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**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

Doc. 1/1, Rev. 0

**Attachment to  
Certificate**

**Registration No.:** SX 60128138 0001  
**Report No.:** 26300167 007

**Organization:** GENEXO Sp. z o.o.  
ul. Gen. Zajaczka 26  
01-510 Warszawa  
Poland

**Scope:**

Design and development, manufacture and distribution of in-vitro diagnostic rapid tests and blood glucose monitoring systems with control solutions, non-sterile medical devices as creams and gels applied to the skin.  
Manufacture and distribution of invasive sample collection devices.  
Distribution of hydrogel patches.

**Certification Body**



**Date: 2018-09-05**

*Maciej Sciera*  
**Maciej Sciera**

