Certificate



Quality Management System EN ISO 13485:2016

Registration No.:

SX 1023624-1

Organization:

GENEXO Sp. z o.o. ul. Gen. Zajączka 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. Manufacture and distribution of invasive sample collection devices, blood pressure monitors, mesh nebulizers, compressor nebulizers, digital and infrared thermometers. Distribution of hydrogel patches.

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.: 84950853-20

Effective date: 2021-02-01

Expiry date: 2024-01-31

Issue date: 2021-01-26





Rafał Byczkowski TR LGA Products GmbH Tillystraße 2 · 90431 Nürnberg · Germany