

EU Certificate

Quality Management System REGULATION (EU) 2017/745 on Medical Devices Annex IX Chapter I, Section 2 and 3 and Chapter III

Registration No.: HZ 1023950-1
Manufacturer: HTL-STREFA S.A.
Adamówek 7
95-035 Ozorków
Poland

EUDAMED Single
Registration No.: PL-MF-000002198

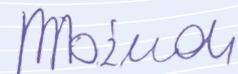
Products: Products of class IIa:
V010401 - LANCETS WITH SAFETY SYSTEMS,
SINGLE-USE
V010402 - LANCETS WITHOUT SAFETY SYSTEMS,
SINGLE USE
A0101010202 - HYPODERMIC PEN NEEDLES,
W/O SAFETY SYSTEMS
A0101010201 - HYPODERMIC PEN NEEDLES,
WITH SAFETY SYSTEMS

Authorized representative(s): Not applicable

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled.

If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.: 84974927-20
Effective date: 2024-09-26
Expiry date: 2029-08-01
Issue date: 2024-09-26



Małgorzata Błażniak
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.



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REGULATION (EU) 2017/745 on Medical Devices
Annex IX Chapter I, Section 2 and 3 and Chapter III**

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Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2024-08-02
1	Transfer scope	2024-09-26

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