2023-01-17
RA 7/2023

Statement

To whom it may concern,

We HTL-STREFA S.A., located at Adamówek 7, 95-035 Ozorków, Poland manufacturer of:

Haemolance Plus safety lancet type 420

hereby confirm that our products are in conformity with European Union Medical Device Directive 93/42/EEC amendment by 2007/47/EC as per EC Certificate reference number: 84587CE01 issued by DEKRA Certification B.V., Arnhem, The Netherlands, Notified Body Identification Number 0344.

Our current EC Certificate is valid until 24 May 2024 therefore, our products indicated on the EC Certificate may still be placed on the EU market in accordance with article 120 of Medical Device Regulation (MDR 2017/745).

In the same time HTL-Strefa S.A. would like to inform that we are in transition period to adopt the requirements of the MDR 2017/745 in EU.

The process of obtaining EC certificate complies with Medical Device Regulation (EU) 2017/745 (MDR) is pending.

Yours sincerely,

Regulatory Affairs Manager

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