MTD
Medical Technology and Devices

HTL STREFA
high tech lab

RA 148/ 2024
2024-05-14

Subject: Notified body change, CE certification, EN ISO 13485 & MDSAP

Dear Valuable Customer,

HTL-STREFA S.A., part of MTD Group, as a manufacturer of **pen needles, safety pen needles, safety lancets, personal lancets and lancing devices** would like to inform you about some regulatory changes for current HTL's products and the related applicable certification.

With the aim of ensuring continuous access to medical devices, HTL took the decision to **change the notified body** involved in conformity assessment procedures in accordance with Medical Device Directive (MDD) and Medical Device Regulations (MDR), certification of Quality Management System as per EN ISO 13485:2016 and Medical Device Single Audit Program (MDSAP) certification acting as Auditing Organization.

The current notified body is **DEKRA Certification B.V. (DEKRA) <0344>** which will be replaced by **TÜV Rheinland LGA Products GmbH (TUV) <0197>.** The latter will take over responsibility for certification under MDR, EN ISO 13485, MDSAP in HTL-STREFA S.A. **TUV** will be responsible also for surveillance activities of the MDD products.

HTL also seizes the opportunity to inform you that under MDR conformity assessment the product lancing device has changed its classification, from class IIa to active device class I, so for production after 26 May 2024, the notified body identification number will no longer appear on a device itself and on the labelling.

We expect to finalize all these regulatory activities for **migration to the new notified body by the end of 2024,** and all activities related to **labelling update will be managed in due time based of specific agreement.**

Thanks to the Regulation (EU) 2023/607 there is no need to update the label due to notified body change, **for MDD products** which are subject of further placing on the market.

We do believe that this change will have positive impacts on the certification processes and will help the implementation of any future developments and/or project.

Best regards,

Stefano Petroni

President of the Management Board