TÜV NORD Polska Sp. z o.o.
ul. Mickiewicza 29
40-085 KATOWICE / Poland
NIP: 634-10-14-590

Katowice, 31 maja 2023

ELEKTRONIKA I ELEKTROMEDYCYNA Sp.j.
ul. Zaciszna 2
05-402 OTWOCK

Statement of Notified Body 227

At the request of the Manufacturer ELEKTRONIKA I ELEKTROMEDYCYNA Sp.j. ul. Zaciszna 2 05-402 OTWOCK dated 17.04.2023., on behalf of the Notified Body TÜV NORD Polska Sp. z o.o., I provide the following information:

- The company ELEKTRONIKA I ELEKTROMEDYCYNA Sp.j. is in the process of conformity assessment according to Regulation 2017/745 (MDR), Annex IX of the following medical devices:

- Multitronic MT-8, Multitronic MT-6, Multitronic MT-5, Multitronic MT-4, Multitronic MT-4E, Multitronic MT-3, Lasertronic LT-3, Sonotronic US-2, Solatronic SLE, Solatronic SL-3, Magnetronic MF-24, Magnetronic MF-12, Magnetronic MF-2, CARBObed

- The scheduled commencement of Phase 1 of the certification audit took place on 30.01.2023.

- The contract between the Notified Body and the Manufacturer was concluded on 21.12.2022 .The contract covers the full cycle of certification according to the Regulation of the European Parliament and of the Council (EU) 2017/745 of April 5, 2017 on medical devices.

The Notified Body TÜV NORD Poland hereby undertakes to inform the President of the Office about serious safety deficiencies found during the conformity assessment.

With best regards,

Kornel Lukaszczyk
Director of Notified Body No. 2274

Digitally signed by Cobzari-Țurcan Rodica
Date: 2023.09.22 09:35:53 EEST
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