

EC DECLARATION OF CONFORMITY

Declaration of Conformity

- Company Name : ERUSLU SAGLIK URUNLERI SAN. AND TIC. A.S.
- Address: 4. Organize Sanayi Bölgesi 83424 No'lu Cadde, Sehitkamil-Gaziantep-TURKIYE

Contact Person: Mr. ÖZCAN MEHMET

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Manufacturer SRN: TR-MF-000039769

- Product: Sleepy Disinfectant Wipes
- Basic UDI-DI: 8682241208SLEEPYHM
- Category: Class I Medical Device

Directive: Regulation (EU) 2017/745 on Medical Devices (MDR)

Declaration: We, ERUSLU SAGLIK, hereby declare under our sole responsibility that the above-mentioned Sleepy Disinfectant Wipes comply with the provisions of Regulation (EU) 2017/745 on medical devices. This compliance has been demonstrated by the assessment of safety and performance according to the requirements of this regulation.

Conformity Assessment: The conformity assessment procedures followed are in accordance with Annex VIII of Regulation (EU) 2017/745. The Sleepy Disinfectant Wipes have been manufactured in accordance with relevant harmonized standards and recognized technical specifications to ensure their compliance.

Technical Documentation: Technical files and clinical evaluations are available for review and have been prepared in accordance with the requirements of Regulation (EU) 2017/745.

Harmonized Standards: TS EN ISO 9001:2015, TS EN ISO 22000:2018, TS EN ISO 14001:2016

Date of Declaration:

25.07.2024



.....Company Stamp.....

