

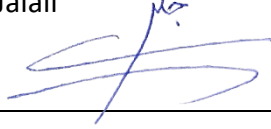
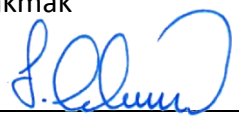
DECLARATION OF CONFORMITY

- 1) Manufacturer Name and Address:** ORYX DIS TICARET LIMITED SIRKETI
Address: Serifali Mah. Baser Sok., No: 32/2,
Umraniye, 34775
Istanbul, TURKIYE
E-mail: Info@Oryxhealthcare.com
Phone: +905359269555
- 2) Authorized Representative Name and Address:** N/A
- 3) Single Registration Number (SRN):** TR-MF-000042900
- 4) Technical File Name/Number:** TF.OX.01/03
- 5) Basic UDI-DI:** 8682520450040
8682520450033
8682520450057
8682520450064
8682520450071
8682520450088
- 6) Product Tradename(s):** ORYX Disposable Concentric EMG Needle
Electrode
- 7) Device Identification:** See Attachment 1
- 8) Classification and Rule(s):** Class: IIa (MDR Annex VIII, Rule 6)
- 9) Intended Purpose:** Diagnosis of neuromuscular disorders via EMG
- 10) Notified Body:** Eurofins Product Testing Italy S.r.l.
- 11) Notified Body Number:** 0477
- 12) Applicable Standards:** See Attachment 2

Declaration Statement:

This declaration of conformity is issued under the sole responsibility of ORYX Co. Ltd. We hereby declare that the above-mentioned device(s) comply with EU MDR 2017/745.

Signed for and on behalf of Manufacturer:

Date of Issue: 2025-03-09	Quality Assurance Manager: Hediye Jalali 	Managing Director: Serkan Cakmak 
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(DISPOSABLE CONCENTRIC EMG NEEDLE ELECTRODE)**Device Identification****Attachment 1 to Annex IV MDR Declaration of Conformity**

REF	Description	Basic UDI-DI
PEN102828	Plastic Hub , 28G with 28mm length	8682520450040
PEN102838	Plastic Hub , 28G with 38mm length	8682520450033
PEN102628	Plastic Hub , 26G with 28mm length	8682520450057
PEN102638	Plastic Hub , 26G with 38mm length	8682520450064
PEN102650	Plastic Hub , 26G with 50mm length	8682520450071
PEN102375	Plastic Hub , 23G with 75mm length	8682520450088

Applicable Standards

Attachment 2 to Annex IV MDR Declaration of Conformity

No	Standard	Title
1	ISO 13485:2016	Medical devices-Quality management system –Requirement for regularity purpose
2	ISO 7864:2016	Sterile hypodermic needles for single use
3	ISO 9626:2016	Stainless steel needle tubing for manufacturing of medical device
4	ISO 10993-1:2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
5	ISO 10993-5:2009	Biological evaluation of medical devices -Part 5:Tests for <i>in vitro</i> cytotoxicity
6	ISO 10993-7:2008	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
7	ISO 10993-10:2023	Biological evaluation of medical devices - Part 10: Test for irritation and skin sensitization
8	ISO 10993-11:2017	Biological evaluation of medical devices - Part 11: Test for system toxicity
9	ISO 10993-23:2021	Biological evaluation of medical devices ñ Part 23: Tests for irritation
10	ISO 14644-1:2015	Clean rooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration
11	ISO 14644-2:2015	Clean rooms and associated controlled environments Part 2: Monitoring to provide evidence of clean room performance related to air cleanliness by particle
12	EN 17141:2020	Cleanrooms and associated controlled environments — Biocontamination control
13	ISO 11135-1:2014	<u>Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices</u>
14	ISO 11737-1:2018	<u>Sterilization of medical devices- Microbiological methods - Part 1: Determination of a population of microorganisms on products</u>
15	ISO11737-2:2020	<u>Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process</u>
16	ISO 11138-2:2017	<u>Sterilization of health care products-Biological indicators Part 2: Biological indicators for ethylene oxide sterilization processes</u>

Applicable Standards

Attachment 2 to Annex IV MDR Declaration of Conformity

No	Standard	Title
17	ISO 14971:2019	Medical devices- Application of risk management to medical devices
18	ISO 15223-1:2021	Medical devices -- Symbols to be used with medical device labels, labeling and information to be supplied -- Part 1: General requirements
19	ISO 11607-1:2020	Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems
20	ISO 11607-2:2020	Packaging for terminally sterilized medical devices -- Part 2: Validation requirements for forming, sealing and assembly processes
21	MEDDEV 2.7.1	Clinical Evaluation of medical device
22	EN 62366:2015	Medical devices - Part 1: Application of usability engineering to medical devices
23	EP:2020	European Pharmacopeia
24	ISO 20417 : 2021	Medical devices — Information to be supplied by the manufacturer
25	ISO/IEC 15459-2:2015	Information technology — Automatic identification and data capture techniques — Unique identification — Part 2: Registration procedures
26	ISO/IEC 15459-3:2014	Information technology — Automatic identification and data capture techniques — Unique identification — Part 3: Common rules
27	ISO 15223-1:2021	Medical devices — Symbols to be used with information to be supplied by the manufacturerPart 1: General requirements
28	EN 62366:2015	Medical devices - Part 1: Application of usability engineering to medical devices
29	IEC60601-1:2020	Medical electrical equipment - ALL PARTS
30	IEC60601-2:2020	Medical electrical equipment - Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators
31	MDCG 2022-5	Guidance on borderline between medical devices and medicinal products under Regulation (EU) 2017/745 on medical devices

Applicable Standards
Attachment 2 to Annex IV MDR Declaration of Conformity

No	Standard	Title
32	MDCG 2021-24	Guidance on classification of medical devices
33	MDCG 2020-7	Post-market clinical follow-up (PMCF) Plan Template A guide for manufacturers and notified bodies
34	MDCG 2022-21	GUIDANCE ON PERIODIC SAFETY UPDATE REPORT (PSUR) ACCORDING TO REGULATION (EU) 2017/745 (MDR)
35	MDCG 2020-3	Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMD
36	MDCG 2020-6	Regulation (EU) 2017/745: Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC
37	MDCG 2021-1	Guidance on harmonised administrative practices and alternative technical solutions until EUDAMED is fully functional
38	MDCG 2018-1	Guidance on BASIC UDI-DI and changes to UDI-DI
39	MDCG 2019-5	Registration of legacy devices in EUDAMED