DECLARATION OF CONFORMITY

Date of Issue:

Manufacturer:

Oryx Co. Ltd:

Dudullu Osb. Mahallei DES 118 Sk. No.1 Umraniye, Istanbul, Tukey.

Tel: +905325610215 Fax: +902163493905 Website: www.OryxHealthcare.com

Notified Body:

MTIC Intercert S.r.l

Notified Body No.: 0068

Via Moscova 11 - 20017 Rho (MI) – Italy.

Tell: +39 02 97071800 Fax: +39 02 9308176 www.mtic-group.org

Device:

DISPOSABLE CONCENTERIC EMG NEEDLE ELECTRODE

SRN

(Single Registeration Number): **(Not applicable yet)**

Basic UDI-DI: **86825204501001UL**

Name of the device(s): **Disposable Concenteric EMG Needle Electrode**

Indication for Use: **S.OX.11**

Classification: **CLASS IIa, Rule 6 Annex IX, MDD 93/42/EEC As Amended by 2007/47/EC**

Conformity Assessment Route: **EU conformity declaration according to Annex II and Annex III**

DEVICE COVERED: DISPOSABLE CONCENTERIC EMG NEEDLE ELECTRODE
With 2 Models and 6 sizes:

1-Metallic Hub

1- MEN102828: 28G with 28mm length
2- MEN102838 28G with 38mm length
3- MEN102628: 26G with 28mm length
4- MEN102638: 26G with 38mm length
5- MEN102650: 26G with 50mm length
6- MEN102375: 23G with 75mm length

2-Plastic Hub

1- PEN102828: 28G with 28mm length
2- PEN102838 28G with 38mm length
3- PEN102628: 26G with 28mm length
4- PEN102638: 26G with 38mm length
5- PEN102650: 26G with 50mm length
6- PEN102375: 23G with 75mm length

DECLARATION OF CONFORMITY

We manufacturer in accordance with MDD 93/42/EEC as amended by 2007/47/EC, do hereby declare that the name devices which are mentioned in page 1 comply with the rules set out in article and claim conformance to Annex II having met the relevant requirements of Annex I of MDD 93/42/EEC as amended by 2007/47/EC.

Conformance is demonstrated by:

EC Annex II certificate Quality System Certificate No: 15882-M having met requirements of ISO 13485:2016.

Note: Applicable harmonized standards are attached in attachment I.

Quality Manager:

Yasemin Akalin

managing director:

Serkan Chakmak

Attachment I:

Applicable Harmonized Standards

No	Standard	Title	Version
1	ISO 13485:2016	Medical devices-Quality management system – Requirement for regularity purpose	4
2	ISO 7864:2016	Sterile hypodermic needles for single use	4
3	ISO 9626:2016	Stainless steel needle tubing for manufacturing of medical device	2
4	ISO 10993-1:2009	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	4
5	ISO 10993-5:2009	Biological evaluation of medical devices -Part 5:Tests for *in vitro* cytotoxicity	3
6	ISO 10993-7:2008	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals	2
7	ISO 10993-10:2010	Biological evaluation of medical devices - Part 10: Test for irritation and skin sensitization	3
8	ISO 10993-11:2017	Biological evaluation of medical devices - Part 11: Test for system toxicity	4
9	ISO 14644-1:2015	Clean rooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration	2
10	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	2
11	ISO 14698-1:2003	Clean room and associated controlled environments-Bio contamination control-Part1:General principle and methods	1
12	ISO 14698-2:2003	Clean rooms and associated controlled environments — Bio contamination control —Part 2: Evaluation and interpretation of bio contamination data	1
13	ISO 16142-1:2016	Recognized essential principles of safety and performance of medical devices -- Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards	1
14	ISO 11135-1:2007	Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices	1

Attachment I:

Applicable Harmonized Standards

No	Standard	Title	Version
15	ISO 11737-1:2006	Sterilization of medical devices- Microbiological methods - Part 1: Determination of a population of microorganisms on products	2
16	ISO11737-2:2009	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process	2
17	ISO 11138-2:2009	Sterilization of health care products-Biological indicators Part 2: Biological indicators for ethylene oxide sterilization processes	2
18	ISO 14971:2012	Medical devices- Application of risk management to medical devices	2
19	ISO 15223-1:2016	Medical devices -- Symbols to be used with medical device labels, labeling and information to be supplied -- Part 1: General requirements	3
20	ISO 11607-1:2009	Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems	1
21	ISO 11607-2:2006	Packaging for terminally sterilized medical devices -- Part 2: Validation requirements for forming, sealing and assembly processes	1
22	MEDDEV 2.7.1	Clinical Evaluation of medical device	4
23	EN 62366:2008	Medical devices - Part 1: Application of usability engineering to medical devices	1
24	EP:2020	European Pharmacopeia	10
25	EN 1041:2008	Information supplied by the manufacturer of medical devices	1