| DECLARATION OF CONFORMITY | | |
|---|---|---|
| MANUFACTURER | **DJO France SAS**<br>Centre Européen de Frêt<br>3 rue de Béthar<br>64990 Mouguerre<br>France | |
| EU AUTHORIZED REPRESENTATIVE | N/A | |
| PRODUCT | TENS Stimulators: Cefar Easy, Cefar Basic, Cefar Primo Pro, Cefar Tens<br>TENS+NMES Stimulators: Cefar Femina, Cefar Peristim Pro, Cefar Rehab X2 | |
| PRODUCT NUMBER LIST | TFL-0003-3_ TENS + NMES Stimulators Parts List_Rev F | |
| CLASSIFICATION | Class IIa, Rule 9 | |
| CONFORMITY ASSESSMENT ROUTE | Annex II – Full Quality Assurance | |
| GMDN CODE | 35372, 46573 | |
| UMDNS CODE | 13-782, 13-775 | |
| WE, THE MANUFACTURER, DJO FRANCE SAS, DECLARE UNDER SOLE RESPONSIBILITY THAT THE ITEM TO WHICH THIS DECLARATION IS RELATED IS IN CONFORMITY WITH:<br>• ALL RELEVANT PROVISIONS OUTLINED IN THE OFFICIAL JOURNAL OF THE EUROPEAN COMMUNITY COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES. THE ITEM COMPLIES WITH ALL RELEVANT PROVISIONS OF THE ANNEX I ESSENTIAL REQUIREMENTS, AS AMENDED UP TO AND INCLUSIVE OF COUNCIL DIRECTIVE 2007/47/EC.<br>• DIRECTIVE 2011/65/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 8 JUNE 2011 ON THE RESTRICTION OF THE USE OF CERTAIN HAZARDOUS SUBSTANCES IN ELECTRICAL AND ELECTRONIC EQUIPMENT (ROHS-2) | | |
| STANDARDS APPLIED | EN ISO 13485:2016/AC:2016 | Medical Devices – Quality management system – Requirements for regulatory purposes |
| | EN ISO 14971:2012 | Medical Devices – Application of Risk Management to Medical Devices |
| | EN 1041:2008 | Information supplied by the manufacturer with medical devices |
| | EN ISO 15223-1:2016 | Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements |
| | ISO 15223-2:2010 | Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 2: Symbol development, selection and validation |
| | ISO 10993-1:2009/AC:2010 | Biological Evaluation of medical devices – Part 1: General requirements for basic safety and essential performance |
| | IEC 62366:2014 | Medical devices – Application of usability |
| | IEC 60601-1:2006/A1:2013 | Medical electrical equipment - Part 1: General requirements for basic safety and essential performance |
| | IEC 60601-1-2:2014 | Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests |
| | EN 60601-1-6:2010 | Medical electrical equipment Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability |

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| | EN 60601-1-11: 2010 | Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment. |
| | IEC 60601-2-10:2012 | Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators |
| | EN 62133: 2013 | Secondary cells and batteries containing alkaline or other non-acid electrolytes. Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications |
| **NOTIFIED BODY** | BSI, Kitemark Court, Davy Avenue,<br>Knowlhill, Milton Keynes MK5 8PP<br>Tel: +44-345-080-9000 | |
| **EC CERTIFICATE(S)** | EC Certificate #:CE 681250<br>Initial certificate Date: 27 July 2018<br>Certificate Effective Date:23 Jan 2019<br>Certificate Expiry Date: 23 January 2024 | |
| **PLACE OF ISSUE** | Mouguerre, France | |
| **SIGNATURE** | SIGNED FOR AND ON BEHALF OF DJO FRANCE SAS,<br>  <br>Name: Tim Allard<br><br>Title: Senior Manager Regulatory (Affairs and Compliance)<br><br>Date: 19 March 2019 | |