Espansione group

MEDICAL DEVICES

CE

DECLARATION OF CONFORMITY

DEVICE	ACCESSORIES	
EYE-LIGHT	EYE LAMP/CE-XXX	MASK LM BLUE/CE-XXX
	EYE MASK/CE-XXX	MASK LM IR/CE-XXX
	MASK LM RED/CE-XXX	HAIR LM/CE-XXX
	MASK LM YELLOW/CE-XXX	BAND LM/CE-XXX

The company Espansione Marketing S.P.A., with Registered and operational headquarter in Blocco 27 – Via degli Orefici 152 - Centergross 40050 Funo, BO – Italia declares under its own responsibility that:

1. The mentioned device complies with the essential requirements of Annex I of Directive 93/42/EEC and subsequent amendments and is certified by the Notified Body KIWA CERMET ITALIA SPA (Identification Number 0476; Via Cadriano 23, 40057 Granarolo dell'Emilia (BO) Italy; Certificate no. MED 23014). The following standards are applied:
    - EN IEC 60601-1:2006+A1:2013
    - EN IEC 60601-1-2:2015
    - EN IEC 60601-1-6:2010+A1:2015
    - EN IEC 60601-1-2-57:2011
    - EN IEC 62304:2006+A1:2015
    - EN IEC 62366-1:2015
    - EN ISO 10993-1:2018
    - EN ISO 15223-1:2016
    - EN 1041:2008+A1:2013
    - EN ISO 14971:2012
    - EN ISO 13485: 2016
2. The device mentioned is to be considered as belonging to the CLASS IIa according to the rules 9 Annex IX of Directive 93/42/EEC and subsequent amendments;
3. All documentation concerning the device is stored in a Product Technical File and shall be kept for a minimum period of 10 years from the last date of manufacture of the product;
4. All phases of construction of the mentioned device meet the requirements set forth in the Quality Management System of the company in accordance with the requirements of Annex II to that Directive;
5. The Quality Management System of the company complies with the requirements specified in the standards ISO 13485 and is certified by the Certifying Body KIWA CERMET (Certificate 4180-M);
6. The Company Espansione Marketing S.P.A. provided a note to the Competent Authority regarding the marketing of the above mentioned device in order to ensure the post-market supervision;
7. The Espansione Marketing S.P.A. company has implemented a procedure to ensure the post-market supervision of the medical devices placed on the market;
8. The validity of this statement is subject to the validity of the above CE certificate No. MED 23014, unless significant changes to the product or its manufacturing process.

Funo (Bo), 20.01.2020

Legal representative Signature
Rodolfo Pomar - CEO