MEIK® EC Declaration of Conformity

issued in accordance with EC Directive 93/42/EEC relating to Medical Devices

Manufacturer: MEIK Limited., 1110, 11/F, Block A, Ming Pao Ind Ctr, 18 Ka Yip St, Chaiwan, Hong Kong
Tel./: (+852) 2851-7400, E-mail: info@MEIK.io http://www.MEIK.io

Authorized Representative: PGT., 3 Chemin de Meursault, 21 190 Auxey Duresses, France

Notified Body: BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Product name: Electrical impedance computer mammograph for mammary gland screening "MEIK"®

represented by Director of MEIK Limited David Bruce Hong declares, that

Electrical impedance computer mammograph for mammary gland screening "MEIK"®

(the composition of the product presented in the User's Manual)

is the medical device class IIa in accordance with EC Directive 93/42/EEC.

Complies with the requirements of the: EC DIRECTIVE 93/42/EEC as amended by Directive 2007/47/EC, EN ISO 13485:2012, EN ISO 14971:2012, ISO 19011:2011, IEC 60601-1-Ed.3.1:2012, ISO 15223-1:2012, EC 60825-1:2014, IEC 62304:2006, EN 60601-1:2012, EN 60601-1-2:2014, EN 60529:2012, EN 60601-1-6:2010, ISO 780;2015, EN ISO 14155:2011.

The Declaration adopted on the basis:

– TEST REPORT ABOUT THE ELECTRICAL SAFETY TEST of the Electrical impedance computer mammograph "MEIK"® No. 414102183AL1 from 28.02.2013 (ITC, Czech Republic).
– TEST REPORT ABOUT THE ELECTROMAGNETIC CONPATIBILITY TEST of the Electrical impedance computer mammograph "MEIK"® No. 414102183AE1 from 22.02.2013 (ITC, Czech Republic).
– FINAL REPORT No. 803601632/2013 from 20.03.2013 (ITC, Czech Republic).
– CERTIFICATE No. CE 695495
– CERTIFICATE EN ISO 13485;2012 No. 16 0113 SJ from 22.09.2016, ITC, Czech Republic.
– Toxicological Conclusion No. 103-13 from 17.06.2013 (National Scientific Center of the toxicological and biological safety of medical devices. TESTING LABORATORY "TOXICOLOGIST" (No ROSS RU.0001.21IM55 from 28.10.2011).
– Report on the Clinical Trial of the Electrical impedance computer mammograph "MEIK"® TU 0442-001-217022999-2013 from 01.09.2014 (RSCRR MOH Russia).
– Declaration of Conformity No ROSS RU. IM02 D01095 from 02.03.2015 (ANO "VNIIIMT", No ROSS RU.0001.11IM02 from 17.01.2011, Russia).
– Registration Certificate No RZN 2014/2214 from 03.02.2015, the The Federal Service on Surveillance in Healthcare (ROSZDRAVNADZOR).

MEIK® does not contain any medicinal substance or drug

„MANUFACTURER" herewith declares that the above-mentioned device meets all applicable provisions of the EC MD Directive 93/42/EEC. The MEIK device is safe under prescribed and reasonably foreseeable conditions of storage and use.

"MANUFACTURER" has implemented measures assuring that the MEIK mammograph of the abovementioned type is safe and fulfills the essential requirements of Annex II, Section 3.2. (quality system requirements) of the Directive 93/42/EEC.

"MANUFACTURER" has instituted and keeps up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means for any necessary corrective actions. The company undertakes to notify through its Authorized Representative in EU member state the Competent Authority on any malfunction or deterioration in the product characteristics, performance or inadequacy in the instruction for use which might lead to death or serious damage of patient's health as well as on technical or medical reason leading to systematic recall of the product by manufacturer.

If the device is modified without the agreement of the undersigned, this declaration becomes invalid in relation to the modified product.

Date of issue: 2019-06-12



Director of MEIK Limited – David Bruce Hong