DECLARATION OF CONFORMITY

European Medical Device Directive 93/42/EEC

Declaration of Compliance with the Essential Requirements of Annex I of Directive 93/42/EEC

Manufacturer	**Medoc Ltd.** 1 Ha' Dekel Street. P.O.Box 423, Ramat Yishai 30095, ISRAEL Tel: +972 (04) 9038800 Fax: +972 (04) 9038808
EC Authorized Representative	**CEpartner4U BV** Esdoornlaan 13 3951 DB Maarn, The Netherlands Mobile: +31 6 516 536 26 Phone: +31 343 442 524 Fax: +31 343 442 162 Email: office@CEpartner4U.com
Harmonized Standards	EN ISO 14971:2012 EN 60601-1:2006/A1:2013 EN 60601-1-2:2015 EN ISO 10993-1:2009/AC:2010 EN 62304:2006/AC:2008

I, the undersigned, hereby declare that the distributed CE marked products, specified in the annexed product list, conform to the product(s) covered by the "CE Marking of Conformity Certificate", reference number ECM18MDD020_MEDOC-17.10, first issued on 21.12.2018 and delivered by *Ente Certificazione Macchine Srl. (ECM) Certification,* Notified Body Identification Number 1282, in accordance with Annex II of the Council Directive 93/42/EEC and statutory instrument 618:2002 bringing the Medical devices directive into English law, concerning medical devices. In addition, we ensure and declare that the distributed CE marked products meet the provisions of the EC-Directive, which apply to them.
This declaration is supported by the Quality System certificate in accordance with Annex II (excluding point 4, Examination of the design of the product) of the EC-Directive.

Date: **12.12.19** Place: **Medoc Ltd**

Signature:

Tal Bornstein
Head of QST Division
Medoc Ltd.

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Medoc
advanced medical systems

ANNEX
Product List

This product list below belongs to the Declaration of Conformity identified by Medoc Ltd. and specifies the CE marked products that Medoc Ltd. intends to distribute in conformity with the provisions of the Council Directive 93/42/EEC concerning medical devices.

The following list identifies the products by model name description.

Model	Classification	Cat. Num.	Product Description	First Placed in the Market
TSA-II	IIa / rule 10	MO 00015	TSA-II Thermal Sensory Analyzer, TSA 2001, Model	Jan, 1998
PATHWAY	IIa / rule 10	MO 00007, MO 00008, MO 00009, MO 00010, MO 00011, MO 00012	Pain & Sensory Evaluation System (including CHEPS - Contact Heat-Evoked Potential Stimulator)	Dec., 2005
AlgoMed FPIX	IIa / rule 10	AS 00300	AlgoMed FPIX Computerized Pressure Algometry	July, 2010
Q-Sense	IIa / rule 10	MO 00013 MO 00013-CPM MO 00014 MO 00014-CPM	Q-Sense Thermal Sensory Analyzer, TSA 2001, Model (CPM / fMRI)	Sep, 2012

Date: **12.12.19**

Signature:

Tal Bornstein
Head of QST Division
Medoc Ltd.

Applicable Documents:

- Essential Requirements # Reg 00038 (Q-Sense)
  # Reg 00001 (PATHWAY)
  # Reg 00089 (TSA-II)
  # Reg 00032 (AlgoMed FPIX)
- Applicable Standard List # DC 00441

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