

# EC CERTIFICATE

Number: 2119134CE01

## Production Quality Assurance

**Directive 93/42/EEC on Medical devices, Annex V**  
(Devices in Class IIa, IIb or III)

Manufacturer:

### **OB-Tools Ltd.**

**4 HaHaroshet st.  
Amira Building  
Nesher 3688104  
Israel**

For the product category(ies)

### **Diagnostic Electromyography system used to measure uterine contractions**

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

# 0344

Documents, that form the basis of this certificate:

**Certification Notice 2119134CN, initially dated 10 December 2010**  
**Addendum, initially dated 10 December 2010**

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for the manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex V of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III or Class IIb devices an additional EC type-examination certificate according to Annex III is mandatory. The necessary information related to the quality assurance system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 1 December 2017  
Issued for the first time: 10 December 2010  
Revised: 16 May 2016  
Reissued: 1 December 2014

DEKRA Certification B.V.



drs. G.J. Zoetbrood  
Managing Director



ing. A.A.M. Laan  
Certification Manager

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DEKRA Certification B.V. is Notified Body with ID no 0344

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# ADDENDUM

Belonging to certificate: 2119134CE01

1/1

## CE MARKING OF CONFORMITY MEDICAL DEVICES

Diagnostic Electromyography system used to measure uterine contractions

Issued to:

**OB-Tools ltd.**  
4 HaHaroshet st.  
Amira Building  
Nesher 3688104  
Israel

This certificate covers the following product(s):

- EUM100Pro (Class IIa)

Initial date: 10 December 2010

DEKRA Certification B.V.

A blue ink signature of drs. G.J. Zoetbrood, consisting of a stylized 'Z' followed by 'oetbrood'.

drs. G.J. Zoetbrood  
Managing Director

A blue ink signature of ing. A.A.M. Laan, consisting of a stylized 'L' followed by 'aan'.

ing. A.A.M. Laan  
Certification Manager

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