

Brainsway Ltd.
19 Hartum St., Bynet Building, 3 rd floor
9777518 Har Hachotzvim, Jerusalem
Israel

Hamburg, 02.12.2014

Confirmation

We herewith confirm that the certification for:

**Brainsway Ltd.
19 Hartum St., Bynet Building, 3 rd floor
9777518 Har Hachotzvim, Jerusalem, Israel**

according to Annex II of Guideline 93/42/EEC with the certificate no. 6106GB410141202

with the scope: Deep Transcranial Magnetic Stimulator (DTMS)

covers the following indications for the treatment of:

- Major Depression (with Anti-depressants and as mono-therapy)
- Bipolar Depression, Schizophrenia - Negative Symptoms
- Parkinson Disease (with antiparkinsonian medications)
- Post-Traumatic Stress Disorder (PTSD)
- Smoking Cessation
- Autism and Asperger's disorder
- Alzheimer's disease
- Chronic diabetic pain
- Obsessive Compulsive Disorder (OCD)
- Multiple Sclerosis (MSC)
- Stroke

With kind regards

Markus Bianchi
Certification Body



Certificate

The Certification Body

**MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany**

herewith confirms that the company

**Brainsway Ltd.
19 Hartum St., Bynet Building, 3 rd floor
9777518 Har Hachotzvim, Jerusalem
Israel**

has introduced and applies a Quality Management System in the area of

**Design and development, production, installation and servicing of
Deep Transcranial Magnetic Stimulation (DTMS) System**

A Quality Audit demonstrated compliance of the Quality Management System with

EN ISO 13485:2012 + AC:2012

The certification assumes that the company is applying and maintaining its
Quality Management System according to the above given standard.

The license of certification is subject to surveillance by MEDCERT.

This certificate is valid until: 16 July 2018
Hamburg, 02 December 2014

A blue handwritten signature, appearing to be "M. Bianchi", written over a horizontal line.

MEDCERT Certification Body
(Markus Bianchi)

Process No.: QS - 6106
Certificate No.: 6106GB438141202



Akkreditiert durch
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln
und Medizinprodukten
ZLG-ZQ-983.99.02-46



EC Certificate of Conformity

The Notified Body

**MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany**

herewith confirms that the company

**Brainsway Ltd.
19 Hartum St., Bynet Building, 3 rd floor
9777518 Har Hachotzvim, Jerusalem
Israel**

has introduced and applies a Quality Management System
for the products / product categories

Deep Transcranial Magnetic Stimulator (DTMS)

An Audit demonstrated compliance of the Quality Management System with

Annex II
excluding section (4)


of the **Council Directive 93/42/EEC concerning Medical Devices.**

The certification assumes that the company is applying and maintaining its Quality Management System according to the above given annex. The license of certification is subject to surveillance by MEDCERT.

This certificate is valid until: 16 July 2018

Hamburg, 02 December 2014

Process No.: QS - 6106
Certificate No.: 6106GB410141202
MEDCERT Identification No.: 0482



MEDCERT Certification Body
(Markus Bianchi)



Akkreditiert durch
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln
und Medizinprodukten
ZLG-ZQ-983.94.13