EC DECLARATION OF CONFORMITY

Manufacturer:

DEYMED Diagnostic s.r.o.
Kudrnáčova 533, 549 31, Hronov, Czech Republic
Reg. No.: 25284584, VAT No.: CZ 25284584

hereby declare that declaration of conformity is issued under the sole responsibility of the manufacturer and that below products:

Electromyograph and applicable accessories

TruTrace EMG

Type: CL 2 / 4 / 8 / 16 and PT 2 / 4 / 8

are in compliance with the relevant harmonized European Union legislation:

Act No. 268/2014 Coll. as amended, on medical devices (Directive 93/42/EEC);
Government Order No. 54/2015 Coll. as amended, on technical requirements on medical devices (Directive 93/42/EEC) and
Government Order No. 481/2012 Coll. as amended, on the restriction of the use of certain hazardous substances in electrical and electronic devices (Directive 2011/65/EU).

Intended purpose: Electromyograph TruTrace types CL and PT are medical devices intended to detection and analyses of biopotentials accompanying neural and muscular activity, spontaneous, voluntary or induced by evoked potentials which may be electrical, tactile, auditory, visual, olfactory etc.

Classification of medical device: Class IIa, active, non-sterile medical device according to Government Order No. 54/2015 Coll. as amended, Annex 9, Rule 10 (Directive, 93/42/EEC Annex IX, Rule 10).

Notified body: 3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovakia, Notified body No. 2265, has performed assessment of quality system according to Government Order No. 54/2015 Coll. as amended, Annex 2 excluding point 8 (Directive 93/42/EEC, Annex II excluding point 4) and issued EC Certificate No. 2018-MDD/QS-030.

Harmonized standard used in relation to which conformity is declared:

ČSN EN 60601-1:1994 / A13:1996
ČSN EN 60601-1-2:2016
ČSN EN 60601-1-6:2010 / A1:2015
ČSN EN 60601-1-1:2001
ČSN EN 60601-1-4:1998
ČSN EN 60601-2-40:1999
ČSN EN ISO 14971:2012
ČSN EN ISO 15223-1:2017
ČSN EN 62304:2007 / A1:2016
ČSN EN ISO 10993-1:2010
ČSN EN 1041 / A1:2014
ČSN EN 50581:2013

The manufacturer further declares that under the normal conditions stated in Instruction of use, the above-mentioned product is safe, effective and suitable for provision of health services and that technical file is stored at the manufacturer.

Place, date of issue: Hronov, 2.1.2019

Seal and sign in behalf of manufacturer:

CE 2265

DEYMED Diagnostic s.r.o.
Kudrnáčova 533, 549 31 Hronov
IČO: 25284584 DIČ: CZ25284584
tel./fax: 491 481 298

Kamil Holub
CEO