

LUXIONA

troll

metalarte

heper⁺

MOONLIGHT⁺

Sagelux

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DEKRA

ISO 9001
ISO 14001



CSQ

MED

EN ISO 13485

EC DECLARATION OF CONFORMITY



We, as the manufacturer, declare under our sole responsibility that medical devices described in this Declaration of Conformity meet the essential requirements of Directives 93/42/EEC and 2007/47/EC

Device: Medical luminary

Type: AGAT CLEAN ISO

Device classification: I

Conformity assessment module: annex VII

Certificate of Conformity number: not applicable

Notified body: not applicable

Applied harmonised standards:

PN-EN ISO 15223-1:2012

PN-EN 1041+A1:2013-12E

PN-EN 60601-1:2011/A11:2011E

PN-EN 60601-1:2011/A1:2014-02E

PN-EN 60601-1-2:2007/AC:2010E

PN-EN 60601-1-6:2010E

PN-EN ISO 14971:2012E

PN-EN 62353:2008E

Moreover, medical devices meet the requirements of the Act of 20 May 2010 on medical devices (Journal of Laws of 2010 No. 107 item 679).

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DYREKTOR ZAKŁADU

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(The Plant Manager)