LUXIONA

troll metalarte heper+ MOONLIGHT+ Sagelux

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DEKRA ISO 9001 ISO 14001

CERTIFIED IQNet MANAGEMENT SYSTEM

CSQ MED EN ISO 13485

EC DECLARATION OF CONFORMITY CE

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:	**RUBIN 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).

Jacentów 2014.04.04

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DYREKTOR ZAKŁADU
Michał Szybalski
(The Plant Manager)