TSU®

TECHNICKÝ SKÚŠOBNÝ ÚSTAV PIEŠŤANY, š.p.
Krajinská cesta 2929/9
921 01 Piešťany, Slovenská republika

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

SNAS
Reg. No. 009/P-018

EC CERTIFICATE
No. 111299070

issued in accordance with the Council Directive No. 93/42/EEC certifies that the medical device of the class IIa,

Germicidal source PROLUX G®

type 60WA/SPH01

manufactured by the company:
Nexa, s.r.o.
Sasinkova 9, 921 41 Piešťany, Slovak Republic

meets the basic requirements specified in the Council Directive No. 93/42/EEC, Annex I., applying to its, with regard to the purpose of use of medical appliances, as specified in harmonized standards.

EN 60601-1:2006/C1:2010, EN 60601-1-2:2008/C1:2010

The Notified Body No. 1299 performed EC conformity assessment of the above medical device in accordance with Annex VII. of the Council Directive No. 93/42/EEC together with the procedure according to Annex VI. A detailed description of the device, documents and procedures of conformity assessment are included in the Final Protocol of product conformity assessment No. 110500090 of July 27. 2011.

The manufacturer must label every medical device with CE 1299 mark.

Date of issue: July 27, 2011
Valid till: July 26, 2016

Technický skúšobný ústav Piešťany, š.p. T/S/U -2- NB č.1299

Ing. Anna Ondrášiková
Product Conformity Assessment Director

Piešťany, 27.07.2011

The rules for use this conformity certificate :

It is forbidden to modifity, amend or rewritethe data in the conformity certificate. This certificate cannot be used as a conformity certificate to product, where a change influencing conformity with the applied normative documents and regulations was done without approval of the TSÚ Piešťany, š.p..

Technický skúšobný ústav Piešťany, š.p.
T/S/U
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NB č.1299

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