



# EC Declaration of Conformity

DARAY Ltd of Marquis Drive, Moira, Derbyshire, United Kingdom DE12 6EJ declare that:

Model name/number	Equipment description
X300 Series	Examination Light & Mounting Variants

In accordance with the following Directives:

## 93/42/EC Medical Devices Directive

and its amending directives

has been designed and manufactured to the following specifications:

Classification: **Class 1 Rule 1**

- 2006/95/EC Low Voltage Directive
- EN ISO 13485:2012
- EN ISO 14971:2012
- EN ISO 9001:2008
- EN 60601-1:2006+A12:2014
- EN 60601-1-2:2007
- EN 60601-2-41:2009
- EN 60598-2-25:1995
- EN 1041:2008+A1:2013

I hereby declare that the equipment named above has been designed to comply with the relevant sections of the above referenced specifications. The unit complies with all essential requirements of the Directives.

DARAY Ltd declares that its Quality System is certified and registered as to complying with ISO 13485:2003 Certificate No. GB10/81526, ISO 9001:2008 Certificate No. GB10/81528 and EC Certificate No. GB10/81527.

Notified body: SGS 202b Worle Parkway, Weston-Super-Mare BS22 6WA

Signed:

Name: **Teresa Street**  
Position: **General Manager**

Issued by DARAY Ltd in the UK  
Date: **31st August 2016**



This declaration applies to CE marked devices produced after the date of issuance of this declaration and before it is either superseded by another declaration or withdrawn.

**DARAY**  
Medical

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