



OEM Tech

LASER ELECTRONICS

OEM Tech LLC. declares under its sole responsibility that the product(s) to which this declaration relates, is in conformity with the following directives, standard(s) and other normative document(s).

List of models:

PCA-10-300V-PD, PCA-10-500V-PD,
PCA-10-700V-PD, PCA-10-1000V-PD,
PCA-10-1500V-PD

Directives:

Medical Device Directive
93/42/EEC
Electromagnetic Compatibility Directive
2014/30/EU
Restriction of Hazardous Substances Directive
2011/65/EU

Product Safety Standards:

EN 60601-1:2006; EN 60601-1:2006/A1:2013

EMC Standards:

EN 55011:2009; EN 55011:2009/A1:2010
EN 61000-3-2:2014

Note: This product is classified as component type for building-in use. The EMC characteristic and safety approval of the final application has to be performed by the end-product manufacturer in accordance to the applicable standards for the end-product.

June 01, 2017


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