

Declaration of Conformance

Manufacturer: Plusoptix GmbH
Address: Neumeyerstraße 48, 90411 Nürnberg, Germany
Product: plusoptiX 09
Model Code: 09
Variants: plusoptiX S09, plusoptiX A09

Classification (MDD, Annex IX): 1 m

We herewith declare under our sole responsibility that the above mentioned products meet the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer and the notified body.

General applicable directives:

Medical Device Directive: Council Directive 93/42/EEC of 29 March 2007 concerning medical devices (MDD93/42/EEC) Annex I.

Standards:

Standards applicable to this product are:

DIN EN ISO 14971; DIN EN 60601-1; DIN EN 60601-1-2; DIN EN ISO 15004

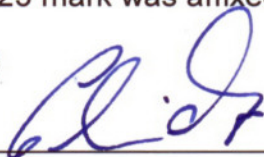
Notified body: TÜV Product Service GmbH
Ridlerstraße 65
80339 München, Germany

Conformity Assessment Route: Annex V.3

Place and Date CE0123 mark was affixed:

Nürnberg, 01.06.2009

Signature _____



Name: Jürgen Schmidt
Position: Managing Director

Plusoptix GmbH

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