

DECLARATION OF CONFORMITY

Opti*Med* Medizinische Instrumente GmbH Ferdinand-Porsche-Straße 11 76275 Ettlingen

hereby declares that the product group

PTA-Balloon Catheter

NyloTrack-18

ORDER CODES:

1780-XXXX

1781-XXXX

1782-XXXX

is classified as Class IIa

and

is in compliance with the applicable stipulations of Council Directive 93/42/EEC dated June 14, 1993 governing medical devices.

Ettlingen, 29 June 2012

OptiMed GmbH

Vanessa Otte Regulatory Affairs OptiMed

Medizinische Instrumente GmbH

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