

Declaration of conformance



Manufacturer
Hedent GmbH
Obere Zeil 6-8

D-61440 Oberursel / Germany

Hedent hereby declares that the product listed below has been tested according to the standards shown on this document. Hedent further acknowledges that The product was found to be in compliance with these standards

Product type: **Denture base resin**
Model number: **PERform powder/liquid**
Brand name: **PERform**
Notified body: DQS Frankfurt am Main 0297
EG medical devices 93/42 EG ,V II

Conforms to:

ISO 1567 DIN EN 27491
DIN ISO 46002 DIN ISO 9002
DIN EN 980 EN ISO 7405
pr EN 1441 DIN EN 30993-1
DIN EN 30993-5 EN ISO 30993-10
DIN EN ISO 13485-2003 DIN 9001/2000
Medical device class 2a

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Oberursel 1st Juli 2006

Stephan Gerlach, President