

DECLARATION OF CONFORMITY

In the sense of the Council Directive 93/42/EEC concerning Medical Devices

Manufacturer:

SOMATEX[®]
MEDICAL TECHNOLOGIES GMBH

Address: Hohenzollerndamm 150/151, 14199 Berlin, Germany

Product: **Tumark[®] Vision**
(REF 271589, 271590)

Classification (MDD, Annex IX): IIb, Rule 8

Herewith we declare under our sole responsibility:

the above mentioned product correspond to the fundamental requirements of Annex I, Annex II excluding (4) of EC- directive for Medical Devices 93/42/EEC.

Notified Body: MedCert Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH,
Pilatuspool 2, 20355 Hamburg, CE 0482

Date CE mark was first affixed: 27th September 2016

The declaration is valid until: 27th May 2024

Place, Date: Berlin, 15th August 2019

Signature:  _____

Name: Christopher Hansche
Position: Quality Manager