



OSYPKA MEDICAL

Berlin, Germany • San Diego, California, USA

## Declaration of Conformity

**in accordance with Medical Device Directive 93/42/EEC Annex II excluding (4)**

We,

Osyпка Medical GmbH  
Albert-Einstein-Strasse 3  
12489 Berlin  
Germany

declare under our sole responsibility, that the medical device

### **Noninvasive Cardiometer ICON® including accessories**

complies with the essential requirements according the Medical Device Directive 93/42/EEC Annex I.

Classification: device class IIa, non-sterile, Annex IX, rule 10

This Declaration of Conformity covers all in our company manufactured loads of the above mentioned device, which are labelled with the CE mark. Start of CE marking was March 31, 2008.

This Declaration of Conformity is based on the Full Quality Assurance System certification with the registration number G1 15 05 39212 018 issued by, the TÜV SÜD Product Service GmbH in Munich, Ridlerstraße 65, 80339 München, identification number 0123. The certification is valid until June 20th, 2020

Berlin, June 22, 2015

Thilo Thümecke  
Regulatory Affairs Manager

Anke Barkowsky  
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