

Declaration of Conformity

We, the

Opis Technology GmbH Sierksstr. 30 01326 Dresden Germany

declare that the product

Opis 60s cable hEar

complies with the essential requirements, which are specified in the directives:

General product safety directive GPSD (2001/95/EC)
Electromagnetic compatibility (EMC) Directive 200411 08/EC
Medical Devices Directive (MDD; 93/42/EEC)
Restriction of the use of certain hazardous substance RL 2011/65/EU:2011

The product of the declaration described above is in conformity with the requirements of the following specifications:

Aron Zeh

EN 60950-1:2006 EN 55022:2010-12 & AC:2011-10, EN 55024:2011 EN60118-4:2006

EN 50581:2012-09

Dresden, 17 Jan 2014,