Declaration of conformity for CE

This is to certify the following product:

X-Ray System 1000 / Arcoma Precision

Manufactured by:

Arcoma AB
Annavägen 1
SE-352 46 Växjö
Sweden

This product is tested and released in conformity with the following requirements for CE marking:

LVFS 2003:11, the Swedish implementation of the Medical Device Directive 93/42/EEC
Classification: Category IIB (according to Annex IX of Council Directive 93/42/EEC)
EC Certificate no: 41311778 Full Quality Assurance System Directive 93/42/EEC on Medical Devices Annex II (3), Notified Body 0413 Intertek Semko AB

and

SFS 2012:861 and KIFS 2008:2, the Swedish implementation of the RoHS II Directive 2011/65/EU
Notified Body 0413 has not been involved in assessing manufacturer processes to ensure RoHS compliance. RoHS compliance is assured under the responsibility of the manufacturer.

The following additionally applies to products with wireless transmission:

PTSFS 2004:7, the Swedish implementation of R&TTE Directive 1999/5/EC
Notified Body 0413 has not been involved in assessing manufacturer processes to ensure compliance. Compliance is assured under the responsibility of the manufacturer.

Växjö, 2020-09-07

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Mattias Rundgren
CEO