

## EU Declaration of Conformity

Manufacturer name	Arcoma AB
Manufacturer Address	Annavägen 1, SE-352 46 Växjö, Sweden
SRN (Single Registration Number)	SE-MF-000012673
Basic UDI-DI	7350008750299D
EMDN Code	Z11031101, Direct Digital Radiology Systems
Name of Device(s)	Arcoma 0180 Intuition
Product code	X-Ray system 0180
Risk Classification	I Ib (MDR 2017/745 Article 2 (4), Annex VIII, rule 10)
Notified body	Intertek Medical Notified Body AB
Notified Body address	PO Box 1103, SE-164 22, Kista, Sweden
Notified Body Identification number	2862
Conformity assessment route	Arcoma AB uses the following procedures for CE-labelling of their products according to Regulation MDR 2017/745: Class I Ib. EU declaration according to Annex IX.

This Declaration of Conformity is issued under the sole responsibility of Arcoma AB. We hereby declare that the medical devices specified above meet the provisions of:

**EU Medical Devices Regulation (MDR 2017/745).**

This declaration is supported by the Quality System approvals issued by Notified Body 2862, certificates 28620148171

**SFS 2016:392, the Swedish implementation of RED 2014/53/EU (in case of wireless**

**transmission).** Notified Body 2862 has not been involved in assessing manufacturer processes to ensure compliance. Compliance is assured under the responsibility of the manufacturer.

**SFS 2012:861 and KIFS 2008:2, the Swedish implementation of the RoHS II Directive**

**2011/65/EU and the amendment 2015/863/EU RoHS III.** Notified Body 2862 has not been involved in assessing manufacturer processes to ensure compliance. Compliance is assured under the responsibility of the manufacturer.

**EU Machinery Directive 2006/42/EC.** Notified Body 2862 has not been involved in assessing manufacturer processes to ensure compliance. Compliance is assured under the responsibility of the manufacturer.

Växjö, 2023-05-04



Mattias Leire  
CEO