Declaration of Conformity

Agfa NV

Septestraat 27, 2640 Mortsel, Belgium

declares that the product

Name: **Ortho CP-GU M**

Application: **General Radiology**

complies with the requirements of the 93/42/EEC Directive (Medical Device) via the Swedish Law Legislation LVFS 2003:11, and that for this Class IIa device the procedures of Annex II have been applied in order to mark the device with the CE-label.

The notified body involved in the above specified procedures is Intertek Semko AB holding the registration number 0413.

Digitally signed by Belan Irina
Date: 2025.08.19 17:10:50 EEST
Reason: MoldSign Signature
Location: Moldova
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In case of product changes not accepted in writing by Agfa, this declaration will expire.
This declaration is valid until 31/12/2028

Date of Issue: 28/03/2024

Koen Vervoort
Head of Quality Assurance & Regulatory Affairs
Agfa NV

AGFA