1260 X-ray GmbH X-RAY ACCESSORIES & MECHANICAL ENGINEERING

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Declaration of EC-Conformity in Accordance with 2017/745, Annex I

We

rego

X-Ray GmbH Stuttgarter Str. 5 D-86154 Augsburg

Declare under our sole responsibility that the product

(PGO) Medical Positioning Aids

Basic UDI-DI: 426040542LGHCA

to which this declaration relates, is in conformity with our production specifications, Quality control system following the regulation (EU) 2017/745, applicable for Class I medical devices with regarts to Art. 120 (3), and will continue to comply with the requirements of regulation EC Directive 93/42/EEC, Annex VII (Class I), as for the items provided there were no significant changes in the design and intend purpose, and it was assessed that no reclassification is needed.

Augsburg, 12.09.2022