

Declaration of EC-Conformity
in Accordance with (EU)
2017/745, Annex IV

We

rego

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

Declare under our sole responsibility that the product

rego Lead Markers (Signs, Numbers and Letters)

Basic UDI-ID : 426040542RBSDF

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 regards 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, 05.07.2022

