

DECLARATION OF CONFORMITY

MANUFACTURER: Retmarker, S.A.
Parque Industrial de Taveiro, Lote 48
3045-504 Coimbra
Portugal

PRODUCT: Retmarker Screening

VERSION: 1.0.27

CLASSIFICATION: Class IIa (based on rule 10, subclause 3.2, of Annex IX of the European Directive 93/42/EEC)

CONFORMITY ASSESSMENT ROUTE: Annex II (without II.4), COUNCIL DIRECTIVE 93/42/EC

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 93/42/EEC FOR MEDICAL DEVICES. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED: Identified in the product technical file

NOTIFIED BODY: TÜV Rheinland LGA Products GmbH
Tillystraße 2
90431 Nürnberg
Germany
Notified Body Nr. 0197



(EC) CERTIFICATE(S): HD 60126657 0001

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SIGNATURE:


João Diogo Ramos
CEO

