

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
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Notified Body Nr. 0197



(EC) CERTIFICATE(S): HD 60126657 0001

START OF CE-MARKING: 28.02.2018

PLACE, DATE OF ISSUE: Coimbra, 18.12.2019

SIGNATURE:


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