DECLARATION OF CONFORMITY

according to annex II without 4, 93/42/EEC

• Manufacturer:
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We herewith declare under sole responsibility that the product

• Name of product family: Resins
• Name of products: Temporary CB
• REF number: FLTCA201, FLTCA301, FLTCB101, FLTCC201
• Product class: Class Ila

meets the relevant requirements of the EC Directive 93/42/EEC concerning medical devices
and is in conformity with the list of applied standards in the technical documentation.

This declaration of conformity is valid until expiration of the EC-Certificate 93/42/EEC (Number HD 60142369 0001) on 26 May 2024 and only together with the related CoA of a batch.

• Notified body:
  TÜV Rheinland LGA Products GmbH
  Tillystraße 2
  90431 Nürnberg, Germany

Notified body: CE 0197

Bremen, 19.06.2020
Place, Date

Signature
Chief Development and Innovation Officer

Signature
Director of Quality Management and Regulatory Affairs

Signature
Managing Director