

DECLARATION OF CONFORMITY

AUROLAB

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We declare that under our sole responsibility that

Product : Poly Glycolic Acid Suture Needles

Brand name : "Polycryl"

CE Mark Approved Models: A6108, A7102, A8104, A9101, A0101

GMDN Code: 13896 - Needle, 13908 - Poly Glycolic Acid Suture

UMDNS Code: For Needles – 12754; For Poly Glycolic Acid Suture - 13908

MD Code: 0302

Lot No. from to

Batch No.:

For all lot numbers / serial numbers which are manufactured according to the specification of the Technical Documentation Issue 09 since 28/04/2022 and are documented in the general batch survey of class III according to Annex IX of Rule 8 in MDD 93/42/EEC meets all the provisions of the directive 93/42/EEC which apply to it.

Applied Standards: Refer list of standards & guidelines in technical file; Technical documentation (TF-SN-01-PGA) Issue 09 dated 28/04/2022

Applied conformity assessment procedure Annex II with requirement of Annex II.4 of MDD 93/42/EEC

Notified Body:

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Notified body number: 2803
Certificate No: 2727C03210501

Issuance Date: 23/05/2021
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Place: Madurai

Date:

Quality Assurance Manager

Form approval:

Issued By: 
(Sr. Quality Assurance Engineer)

Approved By: 
(Sr. Regulatory Affairs Manager)

Date: 28/4/22

Date: 28/04/22

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