Ref. No.: DOC/PFS/07/010221

DECLARATION OF CONFORMITY

Manufacturer:	Curas Ltd. (RO) 69A-B, Raja Uda Business Centre Road 4 12300 Butterworth, Penang Malaysia	
Authorized Representative:	UK Representative Curas Ltd. County Gates, Ashton Rd. Bristol BS3 2JH England	EU Representative Kabomed GmbH Freiheitsstraße 43/1 A-2331 Vösendorf Austria
Medical Device(s):	Sterile Prefilled Syringe All REF numbers as shown in Appendix 1	
Classification:	Class Is, according to Annex IX, Rule 1 of Council Directive 93/42/EEC, as amended by Directive 2007/47/EC	
Conformity Assessment Route:	Directive 93/42/EEC Medical Device (MDD), Annex V	
Standards Applied:	EN ISO 13485:2016, MDD/93/42/EEC	
Product Standard:	ISO 11040-8:2016	
Notified Body:	TUV SUD Product Service GmbH Ridlerstraße 65, 80339 Munich, Germany Identification Number: 0123	

This Declaration of Conformity is issued under the sole responsibility of Curas Ltd.

We hereby declare that the medical device(s) specified above meet the provision of the Council Directive MDD/93/42/EEC for medical devices. This declaration is supported by the Quality System approval to EN ISO 13485 issued by TUV SUD Product Service GmbH.

All supporting documentation is retained at the premises of the manufacturer and its authorized representative.

Authorised Signatory:

Name: Janice Lim
Position: General Manager (Quality Management Representative)
Place and Date: Penang, 01 February 2021

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Appendix 1

List of Curas® Sterile Prefilled Syringes

REF	Product Description
20350	Prefilled Syringe w/10% Glycerine Aqueous, 10ml, Sterile
20351	Prefilled Syringe w/Sterile Water, 10ml

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