

# CERTIFICATE OF EUROPEAN UNION AUTHORISED REPRESENTATIVE



*This is to certify that 3 Gen Inc.*



31521 Rancho Viejo Rd., #104, San Juan Capistrano, CA 92675, USA

has duly registered as a manufacturer as a result of Brexit, with the Irish Competent Authority through its Appointed Authorised Representative in accordance with *Article 14* of the Council Directive 93/42/EEC concerning medical devices (The “Medical Devices Directive”) (93/42/EEC and Medical Devices Regulation 2017/745).

\*\*\*\*\* Applicable ANNEX \*\*\*\*\*

**Annex VII E C Declaration of Conformity,**

\*\*\*\*\* Scope of Supply \*\*\*\*\*

**Quality Assurance System; Registered with ECM, to EN ISO 13485:2016**

\*\*\*\*\*

\*\*\*\*\* Appointment \*\*\*\*\*

**We certify that E C Rep Ltd was appointed as the Authorised Representative on the 12 March 2019**

Signature  
Authorised Representative

Date 28 Nov 2019



**E C Rep Ltd, 5 Fitzwilliam  
Square East, Dublin, D02  
R744, Ireland**

**Certificate No. ECR-3G-AR-01 Valid to 11 March 2022**