

EC Declaration of Conformity - EN

Manufacturers Name: Dita Inc.

Manufacturers Address: 1 Columbia, Aliso Viejo, CA 92656, United States

Authorized Representative Name (if applicable): Dita Eyewear Europe Ltd

Authorized Representative Address (if applicable): Suite 1 Fumbally Court, Fumbally Lane, Dublin D08 TE80 Ireland

Basic UDI-DI:
081002914DITAZ6
081002914LANCIER27
081012195DITAZ8
081100503DITAVZ
081100503LANCIERUH
081227102DITA25
081498102DITA9K

Name of the Device (s): Class 1 frames for Metal Optical with demo lenses
Class 1 frames for Plastic Optical with demo lenses

Classification: Class I as defined by Annex VIII of the Medical Device Regulation MDR 2017/745

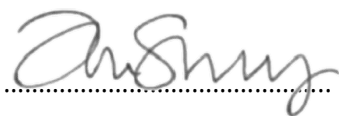
Conformity assessment route: Dita Inc conforms to the following regulations:

Class I: EC conformity declaration according to Annex VIII of the Medical Device Regulation MDR 2017/745 with the specification of International Standard ISO 12870:2016.

Regulation (EC) No 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

This declaration of conformity is issued under the sole responsibility of Dita Inc. We hereby declare that the medical device(s) specified above meets the provision of the Regulation (EU) MDR 2017/745 for medical devices.

Signature:



Place and date (dd.mmm.yyyy) of issue:

Dublin, Ireland 01.04.2025