CATHERINE DE' MEDICI

CATHERINE DE' MEDICI S.R.L.

with registered trade name or registered trade mark Catherine de' Medici,

with registered office in Via Ottavio Revel n. 16 - 10121 TORINO - Italy

VAT Registration Number IT11616810013, registered at the Chamber of Commerce of Torino with REA number TO-1227707 dated November 25th, 2016, duly represented by Giovanni Accongiagioco, as Administrator of the company,

hereby declare that following mentioned products meet the provisions of the Council Regulation EU 2017/745 covering medical devices. All documentation is controlled & retained on company premises.

This declaration of conformity is issued under the sole responsibility of Catherine de' Medici S.R.L.

SRN: validation of EUDAMED in process

a. Basic UDI-DI**: 805384117MET** – Spectacle frames and spectacle frames with tinted lenses for the purpose to be used with corrective lenses non-tinted or tinted made of metal under the brand name Catherine de' Medici - Class I - Rule 1 Annex VIII;

b. Basic UDI-DI: **805384117ACE** – Spectacle frames and spectacle frames with tinted lenses for the purpose to be used with corrective lenses non-tinted or tinted made of plastic under the brand name Catherine de' Medici - Class I - Rule 1 Annex VIII;

c. Basic UDI-DI: **805384117COM** – Spectacle frames and spectacle frames with tinted lenses for the purpose to be used with corrective lenses non-tinted or tinted made of mix materials (metal and plastic) under the brand name Catherine de' Medici - Class I - Rule 1 Annex VIII;

d. Basic UDI-DI**: 805384117LEA** – Spectacle frames and spectacle frames with tinted lenses for the purpose to be used with corrective lenses non-tinted or tinted made of plastic covered with leather under the brand name Catherine de' Medici - Class I - Rule 1 Annex VIII;

e. Basic UDI-DI: **805384117RIM** – Spectacle frames and spectacle frames with tinted lenses for the purpose to be used with corrective lenses non-tinted or tinted made of metal rimless under the brand name Catherine de' Medici - Class I - Rule 1 Annex VIII;

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The products:

- Are comply with European standards EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 10993-1:2009, EN ISO 12870:2018, ISO 12312-1:2013.
- Are in conformity with the EU REGULATION 2017-745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices;
- Are marked "CE";
- Are in conformity with the general obligation of security requested by 2001/95/CEE Directive and all its updates.

Torino, 2022 June 15th

Giovanni Accongiagioco

Administrator

CATHERINE DE' MEDICI srl
Via Ottavio Revel 16 - 10121 TORINO
Tel. 0114462663
Email: info@catherinedemedici1533.com
P. IVA 11616810013