

EU DECLARATION OF CONFORMITY

SPECTACLE FRAMES

Manufacturer:

Name: WENZHOU INTERNATIONAL ECO&TEC COOPERATION CO.,LTD.
Address: 5/F FOREIGN AFFAIRS BLDG, HONGDIAN SOUTH ROAD,
WENZHOU,ZHEJIANG, 325000, CHINA
SRN: CN-MF-000023985

EU Authorised Representative:

Name: Humiss International B.V.
Address: Joop Geesinkweg 701, 1114AB Amsterdam-Duivendrecht, the Netherlands
SRN: NL-AR-000001490

Product Identification:

Product / Trade Name: Spectacle frames Foxy
Model(s) / Reference(s): A01115, A01108, 1057A, 1071, 1074A, 1087A, 1094, 1100,
1107A, A01109, A01110, YHA8004, YHS8039, YHP8050,TA1019, TA1025,TA1024,
TA1021,TA1020, F8779,F8780, 28044,FG1170,FG1276, FP1889,FP1959,FP1978,
FP2000,FP2018,FP2099, FP2100,FP2125,FP2151, FP2503,GV1006,
GV1056,GV1017, GV1035,GV1037, 808

Device Description:

Optical frames without lenses intended for vision correction.

Intended Purpose:

Spectacle frames intended to be fitted with corrective or plano lenses.

We hereby declare that the above-mentioned device(s) comply with Regulation (EU) 2017/745 on medical devices.

This declaration is issued in accordance with Annex IV of Regulation (EU) 2017/745.
This declaration of conformity is issued under the sole responsibility of the manufacturer.

All supporting documentation is kept available to competent authorities upon request.

Basic UDI-DI:

697693337OF6S

Device Group Description:

Spectacle frames(metal and plastic variants) without lenses

Classification:

Class I – non-sterile, no measuring function
According to Rule 1, Annex VIII of Regulation (EU) 2017/745

Conformity Assessment Procedure:

According to Article 52(7) of Regulation (EU) 2017/745

Conformity Route:

Annex II and Annex III of Regulation (EU) 2017/745

Applied Standards:

EN ISO 12870:2018
EN ISO 14971:2019
EN ISO 10993-1:2020
EN ISO 20417:2021

Place: Wenzhou, China

Date: 01/01/2024

Name: Mary Liu

Position: Manager
