LANG-STEREOTEST®

Declaration of Conformity

Declaration of Conformity acc. to Annex IV of the Medical Device Regulation MDR (EU) 2017/745

Manufacturer:

LANG-STEREOTEST AG
Obere Heslibachstrasse 8
CH - 8700 Küsnacht, Switzerland

Single Registration Number SRN of the manufacturer: CH-MF-000029998

European Authorized Representative

EC REP

A. Lang-Lieder
Murstrasse 48
A - 6063 Rum, Austria

Single Registration Number *SRN* of the EC-representative: AT-AR-000013005

The Basic UDI DI according to Annex VI Part C 76 49996943 002 KU

Lang-Stereotest AG declare under their sole responsibility for the issuance of the EU Declaration of Conformity.

Lang-Stereotest AG declare, that the medical devices listed below are medical devices acc. the definition of MDR Article 2 (1) and complies with all applicable requirements of the Medical Device Regulation (EU) 2017/745, especially Annex I:

Product / trade name	*Product Code*	*Reference Number*	*Validity*
LANG-STEREOTEST® I-R	MDN 1207	103	from Lot 001
LANG-STEREOTEST® II-R	MDN 1207	104	from Lot 001

Intended use: Orthoptical products for binocular diagnosis and screening for disorders of stereopsis, to be used by health care professionals.

Risk Class I - according to MDR (EU) 2017/745 Annex VIII, Rule 1.

The conformity assessment is carried out in accordance with Article 52(7) of MDR(EU) 2017/745, the requirements of this EU-Regulation, the state of the art and the harmonized standards have been complied with.

CE MD

The declaration is valid with the date of the signature.

F. Kaiser

Küsnacht, January 1, 2023 Flurina Kaiser, CEO