LANG-STEREOTEST®

Declaration of Conformity

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

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 2017/745/EU, especially Annex I:

Product / trade name	*Product Code*	*Reference Number*	*Validity*
LANG Fixation cube with white handle	MDN 1207	801	from Lot 051
LANG Fixation cube with red handle	MDN 1207	802	from Lot 041
LANG Fixation stick	MDN 1207	901	from Lot 031

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 2017/745/EU Annex VIII, Rule 1.

The conformity assessment is carried out in accordance with Article 52(7) of MDR 2017/745/EU, 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.

Küsnacht, January 1, 2023 Flurina Kaiser, CEO

F. Kaiser