



Declaration of Conformity

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

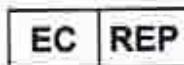
Manufacturer:



LANG-STEREOTEST AG
Obere Heslibachstrasse 8
CH-8700 Küsnacht, Switzerland
CH-MF-000029998

Single Registration Number *SRN* of the manufacturer:

European Authorized Representative



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 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 (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.



The declaration is valid with the date of the signature.

Küsnacht, January 1, 2023

Flurina Kaiser, CEO