



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
CH-MF-000029998

Single Registration Number SRN of the manufacturer:

European Authorized Representative



A. Lang-Lieder
Murstrasse 48
A - 6063 Rum, Austria
AT-AR-000013005

Single Registration Number SRN of the EC-representative:

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:

<i>Product / trade name</i>	<i>Product Code</i>	<i>Reference Number</i>	<i>Validity</i>
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 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.



The declaration is valid with the date of the signature.

Küsnacht, November 1, 2022

Susanne Braun, CEO