## EC DECLARATION OF CONFORMITY (2017/745/EU MEDICAL DEVICE REGULATION)

Name of Manufacturer

: IHC Medikal A.Ş.

Address of Manufacturer

Bahcelievler District Yavuz Road No: 31 Hasanoglan Elmadag

Ankara Turkey

Certification Marking

This EU declaration of conformity is issued under the sole responsibility of the manufacturer.

Declared

Trade Mark

: IHC

SRN No

: 868362832

Basic UDI-DI No : 868362832IHC10HG

**Product Name** Model/Type U0050 **NEGATOSCOPE** U0051 **NEGATOSCOPE NEGATOSCOPE** U0052 U0053 **NEGATOSCOPE** U0054 **NEGATOSCOPE** 

We hereby declare that the medical device specified above comply with essential requirements of Regulation (EU) 2017/745 (MDR)

Applied Annex : Annex-IV Declaration of Conformity (Annex II & III)

Risk Class

U0055

: Class I (Non-Invazive Devices) (Rule 1 Annex VIII of MDR 2017/745)

Date

: Ankara, 08.08.2022

Revision

: 01

**NEGATOSCOPE** 

Hasanoğlan Ba<del>lıçelleyler Mh. Ya</del>vuz Cad. No: 31 Elmadağ //ANKARA Tel: 0312 866 40 40 Faks: 0312 866 40 10 Elmadağ V.D.No: 465 127 1713

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