



EU Declaration of Conformity

According to Medical Device Regulation (MDR) 2017/745

Manufacturers Name: Apple BioMedical Inc.
Manufacturers Address: 8F., No. 12, Ln. 609, Sec. 5, Chong Shin Rd., Sanchong Dist.,
New Taipei City 24159, Taiwan
SRN (Single Registration Number): TW-MF-000038969
Authorized Representative Name: Medical Device Safety Service GmbH
SRN of Authorized Representative: DE-AR-000005430
Authorized Representative Address: Schiffgraben 41, Hannover 30175, Germany
Name of the Device(s): Video Otoscope
Intended Purpose: The MDSCOPE® is a medical device used to observe and
inspect the outer ear canal and tympanic membrane.
Model No. MS102
Catalogue No. MS102(ELB)-EU, MS102(ELBP)-EU, MS102(VEB)-EU,
MS102(DXB), MS102(DX3B), MS102 Elite, MS102-M002
Basic UDI-DI: 471988425MS102GP
Trade Name: Apple Biomedical Inc.
GMDN Code and Term: 12849 Otoscope, direct
Classification: CLASS I
Conformity assessment route: Apple Biomedical Inc. uses the following procedures for the
CE-labeling of their products according the Regulation MDR
2017/745:

Class I: EU conformity declaration according to Annex VIII
Chapter III 4.1 Rule 13

We declare, under our sole responsibility, that the medical devices listed above conform
to the provisions of the following regulation:

Regulation (EU) MDR 2017/745 of the council of 5 April 2017 on medical devices

Above mentioned designation complied with standards as:

EN 60601-1
EN 60601-1-2

EN ISO 14971
EN ISO 15223-1

ISO 13485
EN ISO 20417

Date

Place of Issue

Signature:

2026/06/01

New Taipei

Name: Lydia Jan

Position: Manager of Regulatory Compliance


