



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., Sanzhong Dist.,
New Taipei City 24159, Taiwan
SRN (Single Registration Number): Not available at the time of the declaration
Authorized Representative Name: Medical Device Safety Service GmbH
Authorized Representative Address: Schiffgraben 41, Hannover 30175, Germany
Name of the Device(s): Video Otoscope
Catalogue No. MS101(ELB), MS101(ELBP), MS101(ELBPB), MS101(VEB),
MS101(VXB), MS101(DXB), MS101(DX1), MS101(DX2),
MS101(DX3B), MS101(DX3BP), MS101-002T, MS101-012T,
MS101-013T, MS101-014T, MS101-022T
Basic UDI-DI: 471988425MS101GM
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: EC conformity declaration according to Annex VIII
Chapter III 4.1 Rule 1

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 harmonized standards as:

EN 60601-1:2018	EN ISO 14971:2019	ISO 13485:2016
EN 60601-1-2:2020	EN ISO 15223-1:2016	EN ISO 20417:2021

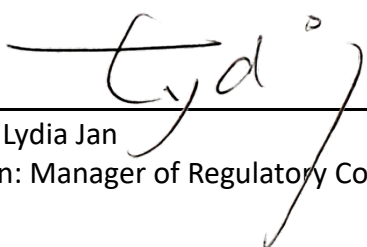
Date

Place of Issue

Signature:

2021/05/24

New Taipei


Name: Lydia Jan

Position: Manager of Regulatory Compliance