APPLE BioMedical Inc.

CE

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):	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