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
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.
Catalogue No.	MS102(ELB)-US, MS102(ELB)-EU,MS102(ELBP)-US, MS102(ELBP)-EU, MS102(VEB)-US, MS102(VEB)-EU, MS102(DXB), MS102(DX3B), MS102-002V, MS102-012V, MS102-013V, MS102-014V, MS102-011T
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: 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 60601-1:2006+A2:2021	EN ISO 14971:2019+A11:2021	ISO 13485:2016
EN 60601-1-2: 2015+A1:2021	EN ISO 15223-1:2021	EN ISO 20417:2021

Date	Place of Issue	Signature:
2021/05/24	New Taipei	Name: Lydia Jan Position: Manager of Regulatory Compliance