APPLE BioMedical Inc.

CE

# EU Declaration of Conformity

According to Medical Device Regulation (MDR) 2017/745

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|---|---|
| **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):** | Speculum |
| **Catalogue No.** | MS101-015, MS101-019 |
| **Basic UDI-DI:** | 471988425SPECULUMP5 |
| **Trade Name:** | Apple Biomedical Inc. |
| **GMDN Code and Term:** | 35348 Speculum, ear |
| **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:<br><br>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:

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| 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<br>Position: Manager of Regulatory Compliance |