

EU DECLARATION OF CONFORMITY

Packaging and Packaging Waste Regulation (PPWR)

Declaration No.	PPWR-AFSERVO-2026-001	Document Status	APPROVED & EFFECTIVE
Product	AF SERVO	Packaging Version	Rev.0
Technical File	TF-PPWR-AFO-001, Rev.0	Place / Issue Date	Hwaseong-si, Republic of Korea / 31 August 2026

1	UNIQUE IDENTIFICATION OF THE PACKAGING Retail/sales packaging for AF SERVO, covering AF SERVO size ranges S, M, L and XL. Packaging Identification / Item Code: AFO-PKG-SYS-01, Rev.0 Packaging System: AF SERVO Packaging System Packaged Product: AF SERVO - AFO-PKG-01 Rev.0 - Individual LDPE Double-Zipper Poly Bag, 250 x 300 mm - AFO-PKG-02 Rev.0 - Product Carton - AFO-LBL-01 Rev.0 - Product Label - AFO-SHIP-01 Rev.0 - Corrugated Shipping Carton
2	MANUFACTURER UDITEL Co., Ltd. Room 401, 4F, 1025-5 Gyeonggi-daero, Byeongjeom-gu, Hwaseong-si, Gyeonggi-do, Republic of Korea 18323
3	RESPONSIBILITY OF THE MANUFACTURER This EU Declaration of Conformity is issued under the sole responsibility of UDITEL Co., Ltd.
4	OBJECT OF THE DECLARATION Packaging system used for AF SERVO. The packaging covered by this declaration comprises the primary, secondary and transport packaging components identified under AFO-PKG-SYS-01, Rev.0. Primary Packaging - AFO-PKG-01 Rev.0 - Product Name: AF SERVO Individual Poly Bag - Material: Low Density Polyethylene (LDPE) - Material Grade / Structure: LDPE Film with Double-Zipper Closure - Dimensions: 250 x 300 mm Color: Transparent / Clear Printing: None - Supplier: Cleanwrap Co., Ltd. Evidence References: SUP-PKG01-001 / INT-PKG01-001 Other Packaging Components - AFO-PKG-02 - Product Carton - AFO-LBL-01 - Product Label - AFO-SHIP-01 - Corrugated Shipping Carton <i>Detailed materials, dimensions, weights and specifications for each packaging component are defined in the controlled PPWR Technical Documentation, Document No. TF-PPWR-AFO-001, Rev.0.</i>

CONFORMITY BASIS & SUPPORTING INFORMATION

5	APPLICABLE EU LEGISLATION The object of the declaration described above is declared to be in conformity with the applicable requirements of: Regulation (EU) 2025/40 of the European Parliament and of the Council of 19 December 2024 on packaging and packaging waste (PPWR). The conformity assessment has been performed against the requirements laid down in or pursuant to Articles 5 to 12, insofar as those requirements are applicable to the packaging concerned at the time it is placed on the EU market. <i>Conformity of the AF SERVO medical device itself with applicable medical-device legislation is managed under separate MDR conformity documentation.</i>
6	STANDARDS / SPECIFICATIONS / EVIDENCE OF CONFORMITY Conformity assessment basis: • Regulation (EU) 2025/40, Article 38 • Annex VII - Module A: Internal Production Control Controlled technical documents and supporting evidence: • TF-PPWR-AFO-001 Rev.0 - AF SERVO PPWR Technical Documentation • AFO-PKG-SYS-01 Rev.0 - AF SERVO Packaging System Specification • AFO-PKG-01 Rev.0 - AF SERVO Individual Poly Bag Specification • AFO-PKG-02 Rev.0 - Product Carton Specification • AFO-LBL-01 Rev.0 - Product Label Specification • AFO-SHIP-01 Rev.0 - Corrugated Shipping Carton Specification • SUP-PKG01-001 - Supplier Product / Material Specification • INT-PKG01-001 - Internal Packaging Verification / Measurement Record <i>Additional supplier declarations, material specifications and test reports are maintained as part of the PPWR Technical Documentation. Where harmonised standards or common specifications become applicable, this declaration and related technical documentation will be reviewed and updated as necessary.</i>
7	NOTIFIED BODY - WHERE APPLICABLE Not applicable. The conformity assessment for the packaging covered by this declaration is performed in accordance with Annex VII, Module A - Internal Production Control of Regulation (EU) 2025/40. UDITEL Co., Ltd. assesses and declares the conformity of the packaging under its sole responsibility. No Notified Body has been involved in the conformity assessment covered by this declaration.
8	ADDITIONAL INFORMATION The technical documentation supporting this declaration is maintained by UDITEL Co., Ltd. Technical Documentation No.: TF-PPWR-AFO-001, Rev.0 The technical documentation includes, where applicable: • Packaging Bill of Materials (BOM) • Packaging material specifications • Supplier material declarations • Material composition information • Information on restricted substances and substances of concern • Packaging dimensions and weight records • Recyclability assessment records • Recycled-content information, where applicable • Packaging minimisation assessment records • Test reports and internal verification records • Packaging drawings and specifications • Change-control records • Risk assessment for packaging non-conformity <i>This declaration shall be reviewed and, where necessary, updated whenever changes to packaging materials, suppliers, construction, dimensions, weight, printing, adhesives, recycled-content information, applicable legislation or relevant technical specifications may affect conformity.</i>

AUTHORISED SIGN-OFF

Place and Date of Issue	Hwaseong-si, Republic of Korea 31 August 2026	Name / Position	Jae Min-Jin Managing Director
Signature		Declaration Status	APPROVED & EFFECTIVE
Technical Documentation	TF-PPWR-AFO-001, Rev.0	Packaging Version	Rev.0