EU DECLARATION OF CONFORMITY

Issued under the sole responsibility of the manufacturer:

Manufacturer Name: Audinor ApS
Registered Address: Benediktevej 5, 3480 Fredensborg, Denmark
Single Registration Number (SRN): DK-MF-000057936
Object of the Declaration:

Product Name: Audinor System 4.0 Transceiver X40 (Part of Audinor System 4.0)
Model / Reference: X40
Basic UDI-DI: 5790002872 15AUDINORX40SA
Risk Classification: Class I (Non-invasive device, pursuant to Annex VIII, Rule 1)
EMDN Code: V030299 (Audiology Accessories - Other)
GMDN Code: 43132 (Hearing aid assistive listening system microphone)
Intended Purpose: An active, battery-powered assistive listening technology and audio streaming accessory. The device captures near-field speech signals via an integrated microphone array, processes the acoustic data, and wirelessly streams a clean digital audio signal directly to compatible digital hearing instruments to improve the signal-to-noise ratio (SNR) and speech intelligibility for hearing-impaired individuals. It may also act as a network bridge for peripheral Audinor transmitters or stream personal audio via an auxiliary line-input.

Declaration of Harmonization:

The object of the declaration described above is in full conformity with the relevant European Union harmonization legislation:

1. **Regulation (EU) 2017/745** of the European Parliament and of the Council of 5 April 2017 on medical devices (MDR), qualifying as a Class I Medical Device pursuant to the classification criteria set out in Annex VIII, Rule 1.
2. **Directive 2014/53/EU** of the European Parliament and of the Council of 16 April 2014 on the harmonization of the laws of the Member States relating to the making available on the market of radio equipment (RED).
3. **Directive 2011/65/EU** of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS), including amending **Directive (EU) 2015/863**.

Applied Standards and Technical Evidence:

Conformity is demonstrated by full compliance, physical laboratory testing, and technical documentation established against the following standards and specifications:

* **Medical & Electronic Safety:** EN/IEC 62368-1
* **Battery Safety:** EN/IEC 62133-2
* **Electromagnetic Compatibility (EMC):**
ETSI EN 301 489-1 V2.2.3 (2019-11) / ETSI EN 301-489-17 V3.3.1 (2024-09)
* **Radio Spectrum Efficiency (2.4GHz & BLE):** EN 300 328 (Tested via separate verification records for Bluetooth Low Energy and Proprietary 2.4GHz protocols).
* **Human RF Exposure / Health**: EN 62479:2010 (Demonstrated via pre-certified embedded RF module suppliers conformity assessment.
* **Chemical Safety & Biocompatibility:** OEKO-TEX® Standard 100 (Product Class I for Baby Articles, tested according to Annex 6) the 2025 raw textile lanyard batch with mechanical safety break-away); EU REACH Regulation EC 1907/2006 for the rigid polymer housing (PC365), silicone protective cover (Shin-Etsu KE-971TU / KE-951U), and push buttons (IR1900).

Sign-off and Authorization:

Signed for and on behalf of Audinor:

Place of Issue: Fredensborg, Denmark
Date of Issue: 2026-08-04
Name: Cecilia Sell Bjorvatn
Function: CEO
Signature: