EU Declaration of Conformity

for the COVVI Wrist Lamination Kit

We herewith declare, under the manufacturer's sole responsibility, that the products described in this document are in conformity with the relevant requirements of **Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices and Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility (recast)** and are manufactured and released according to the provision of the quality management system in force on the date of issue of this declaration and the CE Mark may be affixed.

PRODUCT NAME:	Wrist Lamination Kit
LEGAL MANUFACTURER:	**COVVI LTD,** Unit 4 (Direct House), Quayside Business Park, George Mann Road, Leeds, LS10 1DJ, UK
SINGLE REGISTRATION NUMBER (SRN)	GB-MF-000033926
BASIC UDI-DI	506072613GMN003WY
GLOBAL MEDICAL DEVICE NOMENCLATURE CODE	41086
EUROPEAN MEDICAL DEVICE NOMENCLATURE CODE	Y061899
APPLICABLE LEGISLATIONS AND STANDARDS	As per Appendix I – Applicable Legislations and Standards
CONFIGURATIONS & VARIANTS:	As per Appendix II – Product Listing/Schedule
INTENDED PURPOSE:	The COVVI Wrist Lamination Kit is intended to transmit power and control signals to upper limb exoprosthetic terminal devices.
MEDICAL DEVICE CLASSIFICATION	Class I [Rule 13]
NOTIFIED BODY	N/A
CE CERTIFICATE	N/A
EU AUTHORISED REPRESENTATIVE:	**Advena Limited** Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta
EU AUTHORISED REPRESENTATIVE SRN:	MT-AR-000000234
MEDICAL DEVICE REGULATION ASSESSMENT ROUTE	In conformity with Annexes II and III, the Declaration of Conformity has been drawn up in accordance with Article 19 of Regulation (EU) 2017/745.

Name Simon Pollard **Position** Group CEO

Signed  **Date** 02-Jul-2025 **Place** Leeds, United Kingdom

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

Our statements in this document regarding compliance do not extend to, or apply to any product subjected to unintended contamination, misuse, neglect, or accident

Appendix I – Applicable Legislations and Standards

This product complies with the essential requirements of the following regulations and standards.

1. **Regulations**
    - **UK MDR 2002 –** The Medical Devices Regulations 2002
    - **EU MDD 93/42/EEC –** Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. Medical Device Directive
    - **EU MDR 2017/745** – Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices
    - **21 CFR –** Title 21 Code of Federal Regulations (Parts 800-1299 as applicable)

2. **Standards**
    - **ISO 13485:2016 +A11:2021** – Medical devices. Quality management systems. Requirements for regulatory purposes
    - **ISO 14971:2019 +A11:2021** – Medical devices. Application of risk management to medical devices
    - **ISO/TR 24971:2020** – Medical devices. Guidance on the application of ISO 14971
    - **EN ISO 15223-1:2021** – Medical devices. Symbols to be used with information to be supplied by the manufacturer. General requirements
    - **EN ISO 20417:2021** – Medical devices, Information to be supplied by the manufacturer
    - **IEC 62304:2006/AMD1:2015–** Medical device software. Software life cycle processes
    - **MEDDEV 2.7/1 rev.4 June 2016** – Clinical Evaluation. A guide for manufacturers and notified bodies under directives 93/42/EEC and 90/385/EEC
    - **BS EN 62366-1:2015+A1:2020** – Medical devices. Application of usability engineering to medical devices
    - **IEC 60601-1:2005 + AMD1:2012 + AMD2:2020** – Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.
    - **BS EN 60601-1-2:2015+A1:2021** – Medical electrical equipment - General requirements for basic safety and essential performance. Collateral Standard: Electromagnetic disturbances. Requirements and tests
    - **IEC 60601-1-11:2015/Amd1:2020** – Medical electrical equipment. Part 1-11: General requirements for basic safety and essential performance
    - **EN ISO 10993-1:2018** – Biological evaluation of medical devices. Part 1: Evaluation and testing within a risk management process
    - **ISO 639:2023** – Language code, Codes for the representation of names of languages

3. **Unharmonized standards**
    - **ISO/TC 168 –** Prosthetics and orthotics
    - **ISO 29783 series** – Prosthetics and orthotics
    - **ISO 22523** – External limb prostheses and external orthoses: Requirements and test methods
    - **ISO 8548 series** – Prosthetics and orthotics
    - **ISO 8549 series** – Prosthetics and orthotics
    - **ISO 13405 series** – Prosthetics and orthotics

4. Test Reports & Certification

- **Radio Testing Report No: C13440TR1– Eurofins E&E UK, Castleford Laboratory**
- **Test Report for the FCC EMC: 13433TR1 – Eurofins E&E UK, Castleford Laboratory**
- **EMC Test Certificate No: 13469TC1 – Eurofins E&E UK**

Appendix II – Product Listing/Schedule

Product Code:	Description:	UDI-DI
CAXCOR	COVVI Coaxial Core	5060726131445
CCOUP	COVVI Coupling Piece	5060726131452
CLAMRG-40	COVVI 40mm Lamination Ring	5060726131469
CLAMRG-45	COVVI 45mm Lamination Ring	5060726131476
CLAMRG-50	COVVI 50mm Lamination Ring	5060726131483
CWAKT-40	COVVI 40mm Wrist Lamination Kit	5060726131490
CWAKT-45	COVVI 45mm Wrist Lamination Kit	5060726131506
CWAKT-50	COVVI 50mm Wrist Lamination Kit	5060726131513