UK Declaration of Conformity

for the COVVI Power Supply

We hereby declare, under the manufacturer's sole responsibility, that the products described in this document are in conformity with the applicable provisions of the **Medical Devices Regulations 2002 (SI 2002 No. 618, as amended) and The Electromagnetic Compatibility Regulations 2016 (SI 2016 No. 1091),** and are manufactured and released in accordance with the Quality Management System in force on the date of issue of this declaration. The UKCA marking may be affixed.

PRODUCT NAME:	COVVI Power Supply
LEGAL MANUFACTURER:	**COVVI LTD,** Unit 4 (Direct House), Quayside Business Park, George Mann Road, Leeds, LS10 1DJ, UK
EU SINGLE REGISTRATION NUMBER (SRN)	GB-MF-000033926
BASIC UDI-DI	506072613GMN004X2
GLOBAL MEDICAL DEVICE NOMENCLATURE CODE	36534
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 Power Supply is intended to power externally controlled upper limb prosthetic hands.
MEDICAL DEVICE CLASSIFICATION	Class I [Rule 12]
NOTIFIED BODY	N/A
UKCA CERTIFICATE	N/A
UK APPROVED BODY NAME:	Not Applicable for Class I
UK APPROVED BODY IDENTIFICATION NUMBER:	Not Applicable for Class I
MEDICAL DEVICE REGULATION ASSESSMENT ROUTE	In conformity with the applicable requirements of the Medical Devices Regulations 2002 (SI 2002 No. 618, as amended), commonly referred to as UK MDR 2002.

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

- **IEC 62133-2 Test Report No: T211-0785/21 - SIQ Ljubljana**
- **IEC 62133-2 Test Report No: T211-1057/19 - SIQ Ljubljana**
- **IEC 62133-2 Test Certificate No: SI-7716 - SIQ Ljubljana**
- **Safety testing of COVPS -1600 and COVPS 2600 Report No: G5615TR2 – Eurofins E&E UK**
- **Safety testing of COVPS -1600 and COVPS 2600 Report No: G5813TR2 – Eurofins E&E UK**
- **UN38.3 TRANSPORT OF DANGEROUS GOODS - Lithium metal and lithium ion batteries Report No: BA-4786908576-A-1 - UL Solutions**
- **UN38.3 TRANSPORT OF DANGEROUS GOODS - Lithium metal and lithium ion batteries Certificate No: 20150610- 4786908576 - FB2S1P18650-26 - UL Solutions**
- **IP44 Test Report No: CML-TR20210204.4 - Eurofins E&E CML**
- **IP44 Test Certificate No: CML-TR20210204.4 - Eurofins E&E CML**

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Appendix II – Product Listing/Schedule

Product Code:	Description:	UDI-DI
COVPS-1600	COVVI Power Supply - 1600mAh	5060726131544
COVPS-2600	COVVI Power Supply - 2600mAh	5060726131575
COVSB-1600	COVVI Spare Battery - 1600mAh	5060726131520
COVSB-2600	COVVI Spare Battery - 2600mAh	5060726131582
COVSWC	COVVI Spare Wall Charger	5060726131537
LNCOVPS-1600	COVVI Loan Power Supply – 1600mAh	5060726132213
LNCOVPS-2600	COVVI Loan Power Supply – 2600mAh	5060726132220