

EU Declaration of Conformity

for the COVVI Power Supply



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:	COVVI Power Supply
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	506072613GMN004X2
GLOBAL MEDICAL DEVICE NOMENCLATURE CODE	36534
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 Power Supply is intended to power externally controlled upper limb prosthetic hands.
MEDICAL DEVICE CLASSIFICATION	Class I [Rule 13]
NOTIFIED BODY	N/A
CE CERTIFICATE	N/A
EU AUTHORISED REPRESENTATIVE:	Advena Limited Tower Business Centre, 2 nd 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

COVVI

COVVI House, 4 Quayside Business Park, George Mann Road, Leeds, LS10 1DJ
Switchboard: **+44 (0)203 9499 500** Website: www.covvi.com Website: www.covvi-robotics.com

Registered in England No: 10932714 | VAT Registration No: 278 6409 59 | Registered Office Address: Direct House, 4 Quayside Business Park, Hunslet, Leeds, West Yorkshire, LS10 1DJ

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

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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 (Configurations and Variants)

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

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