EU Declaration of Conformity

for the COVVI Glove Kit 2

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 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 Glove Kit 2
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	506072613GMN2GK2V
GLOBAL MEDICAL DEVICE NOMENCLATURE CODE	64736
EUROPEAN MEDICAL DEVICE NOMENCLATURE CODE	Y090312
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 Glove Kit 2 is an accessory intended to be worn with the COVVI Hand (Friction and Straight Wrist) to protect it from external contaminants and maintain device integrity.
MEDICAL DEVICE CLASSIFICATION	Class I [Rule 1]
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** 19-Feb-2026 **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 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)
    - **Ukrainian Technical Regulations**- Resolution of the Cabinet of Ministers of Ukraine No. 753 ("On Approval of the Technical Regulation on Medical Devices")
    - Australia Regulation- **Therapeutic Goods Administration**
    - New Zealand Regulation- **Medsafe** (New Zealand Medicines and Medical Devices Safety Authority)
    - Health Canada- **Medical Devices Regulations** (SOR/98-282)
    - Argentina Regulations (**ANMAT**)- The National Administration of Drugs, Foods and Medical Devices
    - Mexico (**COFEPRIS**)- Federal Commission for the Protection against Sanitary Risk
    - Brazil Regulations (**ANVISA**, RDC No. 751/2022)- ANVISA (The National Health Surveillance Agency
    - Dubai (Dubai Health Authority (DHA))- Ministry of Health and Prevention (**MOHAP**)
    - Federal Law No. 323-FZ, Article 38- Ministry of Health of the Russian Federation (**Minzdrav**)
    - Swissmedic – **Swiss Agency for Therapeutic Products**- Medical Devices Ordinance (MedDO, SR 812.213)

2. **Standards**
    - **ISO 13485** – Medical devices. Quality management systems. Requirements for regulatory purposes
    - **ISO 14971** – Medical devices. Application of risk management to medical devices
    - **ISO/TR 24971** – Medical devices. Guidance on the application of ISO 14971
    - **EN ISO 15223-1** – Medical devices. Symbols to be used with information to be supplied by the manufacturer. General requirements
    - **EN ISO 20417** – Medical devices, Information to be supplied by the manufacturer
    - **IEC 62304–** Medical device software- Software life cycle processes
    - **BS EN 62366-1** – Medical devices. Application of usability engineering to medical devices
    - **IEC 60601-1** – Medical electrical equipment — Part 1: General requirements for basic safety and essential performance
    - **BS EN 60601-1-2** – Medical electrical equipment - General requirements for basic safety and essential performance. Collateral Standard: Electromagnetic disturbances. Requirements and tests
    - **IEC 60601-1-11**– Medical electrical equipment. Part 1-11: General requirements for basic safety and essential performance
    - **EN ISO 10993-1** – Biological evaluation of medical devices. Part 1: Evaluation and testing within a risk management process
    - **ISO 639** – 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

Appendix II – Product Listing/Schedule

Product Code:	Description:	UDI-DI
G2LLCA	COVVI Glove Kit 2 - Left Hand Large Carbon	5060726132718
G2LLTG	COVVI Glove Kit 2 - Left Hand Large Titanium Grey	5060726132725
G2LLWH	COVVI Glove Kit 2 - Left Hand Large White	5060726132732
G2LMCA	COVVI Glove Kit 2 - Left Hand Medium Carbon	5060726132749
G2LMRG	COVVI Glove Kit 2 - Left Hand Medium Rose Gold	5060726132756
G2LMTG	COVVI Glove Kit 2 - Left Hand Medium Titanium Grey	5060726132763
G2LMWH	COVVI Glove Kit 2 - Left Hand Medium White	5060726132770
G2LSCA	COVVI Glove Kit 2 - Left Hand Small Carbon	5060726132787
G2LSRG	COVVI Glove Kit 2 - Left Hand Small Rose Gold	5060726132794
G2LSTG	COVVI Glove Kit 2 - Left Hand Small Titanium Grey	5060726132800
G2LSWH	COVVI Glove Kit 2 - Left Hand Small White	5060726132817
G2RLCA	COVVI Glove Kit 2 - Right Hand Large Carbon	5060726132824
G2RLTG	COVVI Glove Kit 2 - Right Hand Large Titanium Grey	5060726132831
G2RLWH	COVVI Glove Kit 2 - Right Hand Large White	5060726132848
G2RMCA	COVVI Glove Kit 2 - Right Hand Medium Carbon	5060726132855
G2RMRG	COVVI Glove Kit 2 - Right Hand Medium Rose Gold	5060726132862
G2RMTG	COVVI Glove Kit 2 - Right Hand Medium Titanium Grey	5060726132879
G2RMWH	COVVI Glove Kit 2 - Right Hand Medium White	5060726132886
G2RSCA	COVVI Glove Kit 2 - Right Hand Small Carbon	5060726132893
G2RSRG	COVVI Glove Kit 2 - Right Hand Small Rose Gold	5060726132909
G2RSTG	COVVI Glove Kit 2 - Right Hand Small Titanium Grey	5060726132916
G2RSWH	COVVI Glove Kit 2 - Right Hand Small White	5060726132923