

REACH COMPLIANCE STATEMENT



for the COVVI Wrist Lamination Kit

We herewith declare, under the manufacturer's sole responsibility, that the products described in this document have been evaluated against **Regulation (EC) 1907/2006 of the European Parliament, "Registration, Evaluation, and Authorization of Chemicals (REACH), as interpreted by EU Court of Justice decision C-106/14 of 10 September 2015.** The compliance status of the product is confirmed by the sections below.

PRODUCT NAME:	Wrist Lamination Kit
LEGAL MANUFACTURER:	COVVI LTD, Unit 4 (Direct House), Quayside Business Park, George Mann Road, Leeds, LS10 1DJ, United Kingdom
CONFIGURATIONS & VARIANTS:	As per Appendix I - Product Listing/Schedule
FUNCTION:	The COVVI Wrist Lamination Kit is intended to transmit power and control signals to upper limb exoprosthetic devices.
ARTICLE 33 OF EU REGULATION 1907/2006	The product(s) described in this document, as well as any articles contained within the product(s), DO NOT CONTAIN any of the latest 247 REACH - Substances of Very High Concern (SVHC) as updated by ECHA on January 21, 2025 (https://echa.europa.eu/candidate-list-table) in concentrations above 0.1% w/w (1000 ppm).
ARTICLE 67 OF EU REGULATION 1907/2006	The product(s) referenced above have been evaluated for the presence of restricted substances listed in REACH Annex XVII and does not contain any of the restricted substances within the scope of the restriction condition.

*An article is any item within a part or component of the product which during production is given a special shape, surface or design that determines its function to a greater degree than its chemical composition. An example of articles within an electronic component would be the leads of a through-hole capacitor. For more information, please refer to Example 21 of the EU Chemicals Agency "Guidance for Requirements on Substances in Articles" (https://echa.europa.eu/documents/10162/23036412/articles_en.pdf/cc2e3f93-8391-4944-88e4-efed5fb5112c)

COVVI Ltd collaborates closely with its suppliers to identify any non-compliance issues and works to eliminate them if discovered. Customers affected by any non-compliance will be notified immediately.

Additional information on the European Union's REACH regulation can be found here: <https://echa.europa.eu/regulations/reach/understanding-reach>

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 REACH compliance do not extend to, or apply to any product subjected to unintended contamination, misuse, neglect, or accident.

COVVI

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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

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Appendix I - Product Listing/Schedule (Configurations and Variants)

Product Code:	Description:
CAXCOR	COVVI Coaxial Core
CCOUP	COVVI Coupling Piece
CLAMRG-40	COVVI 40mm Lamination Ring
CLAMRG-45	COVVI 45mm Lamination Ring
CLAMRG-50	COVVI 50mm Lamination Ring
CWAKT-40	COVVI 40mm Wrist Lamination Kit
CWAKT-45	COVVI 45mm Wrist Lamination Kit
CWAKT-50	COVVI 50mm Wrist Lamination Kit

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