

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 in accordance with **UK REACH, retained in UK law through The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (SI 2019 No. 758)**, including the retained text of **Regulation (EC) No 1907/2006**, as interpreted and applied under the authority of the UK Health and Safety Executive (HSE). 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 UK REACH Substances of Very High Concern (SVHCs), as listed by the UK HSE, in concentrations above 0.1% w/w (1000 ppm), as of January 2025.
ARTICLE 67 OF EU REGULATION 1907/2006	The product(s) referenced above have been evaluated for the presence of substances restricted under Annex 17 of UK REACH and do not contain any of the restricted substances in a manner that exceeds the scope of the restriction conditions.

*An "article" is any object which during production is given a special shape, surface, or design that determines its function to a greater degree than its chemical composition. <https://www.hse.gov.uk/reach/candidate-list.htm>

COVVI Ltd collaborates closely with its suppliers to monitor any restricted or non-compliant substances and takes corrective action if required. Customers affected by any non-compliance will be notified immediately.

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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