

# REACH COMPLIANCE STATEMENT



## for the COVVI Hand

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.

<b>PRODUCT NAME:</b>	COVVI Hand
<b>LEGAL MANUFACTURER:</b>	<b>COVVI LTD,</b> Unit 4 (Direct House), Quayside Business Park, George Mann Road, Leeds, LS10 1DJ, United Kingdom
<b>CONFIGURATIONS &amp; VARIANTS:</b>	As per Appendix I - Product Listing/Schedule
<b>FUNCTION:</b>	The COVVI Hand is intended for individuals with unilateral or bilateral upper limb loss or congenital limb deficiency. It is designed exclusively for use in exoprosthetic fittings of the upper limbs, providing functional and assistive support to users.
<b>ARTICLE 33 OF EU REGULATION 1907/2006</b>	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 ( <a href="https://echa.europa.eu/candidate-list-table">https://echa.europa.eu/candidate-list-table</a> ) in concentrations above 0.1% w/w (1000 ppm).
<b>ARTICLE 67 OF EU REGULATION 1907/2006</b>	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](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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Switchboard: +44 (0)203 9499 500 Website: [www.covvi.com](http://www.covvi.com) Website: [www.covvi-robotics.com](http://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 - Product Listing/Schedule (Configurations and Variants)

Product Code:	Description:
CV1LSQBLWH	COVVI Left Small Hand - Black Glove White Cover
CV1LMQBLWH	COVVI Left Medium Hand - Black Glove White Cover
CV1LLQBLWH	COVVI Left Large Hand - Black Glove White Cover
CV1RSQBLWH	COVVI Right Small Hand - Black Glove White Cover
CV1RMQBLWH	COVVI Right Medium Hand - Black Glove White Cover
CV1RLQBLWH	COVVI Right Large Hand - Black Glove White Cover
CV1LSQBLCA	COVVI Left Small Hand - Black Glove Carbon Cover
CV1LMQBLCA	COVVI Left Medium Hand - Black Glove Carbon Cover
CV1LLQBLCA	COVVI Left Large Hand - Black Glove Carbon Cover
CV1RSQBLCA	COVVI Right Small Hand - Black Glove Carbon Cover
CV1RMQBLCA	COVVI Right Medium Hand - Black Glove Carbon Cover
CV1RLQBLCA	COVVI Right Large Hand - Black Glove Carbon Cover
CV1LSQBLRG	COVVI Left Small Hand - Black Glove Rose Gold Cover
CV1LMQBLRG	COVVI Left Medium Hand - Black Glove Rose Gold Cover
CV1RSQBLRG	COVVI Right Small Hand - Black Glove Rose Gold Cover
CV1RMQBLRG	COVVI Right Medium Hand - Black Glove Rose Gold Cover
CV1LSQBLTG	COVVI Left Small Hand - Black Glove Titanium Grey Cover
CV1LMQBLTG	COVVI Left Medium Hand - Black Glove Titanium Grey Cover
CV1LLQBLTG	COVVI Left Large Hand - Black Glove Titanium Grey Cover
CV1RSQBLTG	COVVI Right Small Hand - Black Glove Titanium Grey Cover
CV1RMQBLTG	COVVI Right Medium Hand - Black Glove Titanium Grey Cover
CV1RLQBLTG	COVVI Right Large Hand - Black Glove Titanium Grey Cover
LN1LSQ	COVVI Loan Left Small Hand
LN1RSQ	COVVI Loan Right Small Hand
LN1LMQ	COVVI Loan Left Medium Hand
LN1RMQ	COVVI Loan Right Medium Hand
LN1LLQ	COVVI Loan Left Large Hand
LN1RLQ	COVVI Loan Right Large Hand



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