



## DECLARATION OF CONFORMITY

Chiaro Technology Ltd, 63-66 Hatton Garden, London, EC1N 8LE United Kingdom, hereby declares under its sole responsibility that the

Product Name:	Elvie Curve
Model Number(s):	EC01
EAN:	5060442520547
Description:	Non-Powered Breast Pump

EU Authorised Representative	AR Experts, Amerlandseweg 7, 3621 ZC Breukelen, Netherlands
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This declaration of conformity is issued under the sole responsibility of Chiaro Technology Limited. We hereby declare that the medical device specified above meets the provision of the following Regulations and Directives:  
Regulation 1935/2004 on material and articles intended to come into contact with food  
Regulation 10/2011 on plastic materials and articles intended to come into contact with food  
Directive 2001/95/EC on General Product Safety  
Regulation 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

All supporting documentation is retained at the premises of the manufacturer.

Hereby declare that:

Equipment: Chiaro, Elvie Curve, Non-Powered Breast Pump

is in conformity with the applicable requirements of the following documents:

Ref No.	Title	Reference
ISO10993-1:2009	Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process	N/A
ISO10993-5: 2009	Biological evaluation of medical device Part 5: Tests for in vitro cytotoxicity	RPT-003475
ISO10993-10:2010	Biological evaluation of medical device Part 10: Test for irritation and skin sensitization	RPT-003476
EC 1907/2006	1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)	RPT-003478 & RPT-003477
EC 1935/2004	Regulation on material and articles intended to come into contact with food	RPT-003478
EU 10/2011	Regulation on plastic materials and articles intended to come into contact with food	RPT-003478

Legal Manufacturer

Chiaro Technology Ltd

63-66 Hatton Garde, London, EC1N 8LE

London

Place of Issue

Name of Authorised Signatory:

Alastair Traquair

Role:

Director of Quality and Regulatory Affairs

Signature:

*Alastair Traquair*

Date of Issue:

12 Dec 2023

**CHIARO**  
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Registered company name - Chiaro Technology Ltd  
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