



## UK 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 Stride
Model Number(s):	EB01

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 Directives:  
 Radio Equipment Regulations 2017  
 The Waste Electrical and Electronic (WEEE) Regulations 2013  
 UK REACH 2021  
 Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012  
 All supporting documentation is retained at the premises of the manufacturer.

Hereby declare that:

Equipment: Elvie Stride Breast Pump

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

Ref No.	Title	Edition/Date	Evidence
2011/65/EU	Directive 2011/65/EU on the restrictions of the use of hazardous substances in electrical and electronic equipment (recast)	2011	RPT-001544
2012/19/EU	Directive 2012/19/EU on waste of electrical and electronic equipment (WEEE)	2012	RPT-001544
BS EN 60601-1	Medical Electrical Equipment Part 1: General Requirements of Safety	2006	RPT-000519
EN 60601-1-2	Medical Electrical Equipment Part 1-2: General Requirements of Safety. Collateral Standard Electromagnetic Compatibility – Requirements and Tests.	2007	RPT-000520
ISO10993-5	Biological evaluation of medical device Part 5: Test in vitro cytotoxicity	ISO10993-5(2009)/ISO10993-12(2012), #UB/2015/50824_Jun 17, 2015	RPT-000523
ISO10993-10	Biological evaluation of medical device Part 10: Test for irritation and skin sensitization	ISO10993-10 (2010), #UB/2015/50824A-02_Jul 20, 2015, #UB/2015/50824A-01_Jul 02, 2015	RPT-000521, RPT-000522
EN300328	Electromagnetic compatibility and Radio spectrum Matters (ERM); Wideband transmission systems	V1.9.1/Jul.23, 2015	RPT-001684
IEC 62133:2012	Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications	Sep 06, 2015	RPT-000475
IEC60529	Protection provided by enclosures (IPX7)	IEC60529(2013)/Jan 27,2105 #SHIN1501003227MR	RPT-000519
EN62479	Assessment of the compliance of low power electronic and electrical equipment	V2010/Jul.23, 2015	RPT-001737

REG-001745 Rev A

EC 1907/2006	SVHC of the REACH Regulation	V1907/2006(2014/12/17)_2015/ 5/29	RPT-001546
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Signed for and on behalf of:

Chiaro Technology Ltd  
63-66 Hatton Garden, London, EC1N 8LE

LEGAL MANUFACTURER:

Place of issue: London  
Date of issue: 11th July 2022  
Name: Alastair Traquair  
Position: Head of Quality

Signature: *Alastair Traquair*