

# Declaration of Conformity

We,

**Spiracle Technology**

10601 Calle Lee, #190

Los Alamitos, CA 90720 U.S.A.

Tel: (714) 418-1091 Fax: (714) 418-1095

Declare that the product(s) listed below:

	MVP (Manual Vacuum Pump)	
<b>Product</b>	FERNO2, MVP (Manual Vacuum Pump)	
<b>Model</b>	T60540	
<b>Type/Group</b>	Refer to Below Codes Listing	
<b>Item No.</b>	<b>Name</b>	<b>Codes Listing No.</b>
1	Spiracle Technology, FERNO2, MVP (Manual Vacuum Pump)	T60540

which this declaration relates, is in conformity with the following standards or other normative documents :

## STANDARD/REQUIREMENTS

EN ISO 13485

EN ISO 14971:2019

EN ISO 10651:2009

EN ISO 5356-1:2004

EN ISO 10079-2:2009

EN ISO 10993-1:2018

EN ISO 10993-5:2009

EN ISO 10993-10:2013

EN980:2008

EN1041:2008+A1:2013

CE MDD: Cert. by mfg.

2007/47/EC

ASTM F920-93

FDA Establishment 2030745

FDA 510(k) Class 1 - Not Applicable (exemption)

CE Class 1, Rule 1, Annex VIII, Regulation (EU) 2017/745

Issued by,

**Spiracle Technology**

10601 Calle Lee, #190

Los Alamitos, CA 90720 U.S.A.

Date: 01-15-2025



Michael Sarné

Managing Director