

EU DECLARATION OF CONFORMITY

This declaration of conformity is issued under the sole responsibility of the manufacturer

Issuer:

Business Name: HighFiv
Address: Wentelploeg 30, 8314BD, Bant, The Netherlands

Manufacturer:

Business Name: HighFiv
Address: Wentelploeg 30, 8314BD, Bant, The Netherlands

Authorized Representative:

Business Name: APEX CE SPECIALISTS LIMITED
Address: UNIT 3D NORTH POINT HOUSE, NORTH POINT BUSINESS PARK, NEW MALLOW ROAD, CORK, T23 ATP
Country: Ireland

Product(s):

Name: Thermometer Probe Cover
Brand: HighFiv
ASIN: 8719326927800



We declare that the product described above, which this declaration of conformity refers to, is in conformity with the relevant Union harmonization legislation:

- **MDR Directive – 2017/745/EU**

The medical device has been assigned to **Class I**.

Conformity Assessment Procedure: Annex II + Annex III of Regulation 2017/745/EU.

through the technical standards/specifications specify below:

- EN ISO 14971: 2019
- EN ISO 15223-1: 2016
- EN 1041:2008+A1: 2013
- ISO 10993-1: 2018
- EN ISO 10993-5:2009
- EN ISO 10993-10:2013

-Signed for and on behalf of:

APEX CE SPECIALISTS LIMITED
(Republic of Ireland)

Bant, City – 02-07-2023
(place and date of issue)

Manager Schlepers, Niek
(name, function)

(signature)

This DoC compliance statement document is not authorized for commercial use.

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