
	F 26-7 EC Declaration of Conformity	v1
		14/04/2020

Template Version	Nature of change	Date
1	Initial version	14/04/2020

	F 26-7	v1
	EC Declaration of Conformity	14/04/2020

This is to certify that following Medical Devices:

Healthentia

are manufactured and sold by

INNOVATION SPRINT

Clos Chapelle-aux-Champs 30 - bte 1.30.30
1200 Brussels, Belgium

These products:

1. Are classified as Class I devices per Rule 12 of Annex IX of the Medical Device Directive 93/42/EEC as amended and the Royal Decree dated March 18th 1999 as national transposition.
2. Comply with the Essential Requirements of Annex I the Medical Device Directive 93/42/EEC as amended and the Royal Decree dated March 18th 1999 as national transposition.
3. This compliance has been properly documented using a checklist created from Annex I of the European Medical Device Directive and the Royal Decree dated March 18th 1999 as national transposition, linked to all supporting Technical Documentation. This documentation included both product specific and process (Quality System) specific documents.
4. Are manufactured in facilities having a Quality System in place based on EN ISO13485: 2016.
5. This Declaration is issued by INNOVATION SPRINT and has unlimited time validity.
6. This Declaration of Conformity is signed below, certifying these requirements have been met and documented.

For INNOVATION SPRINT, made in Brussels, BELGIUM the 14th April 2020.


Dr. Sofoklis Kyriazakos
CEO