

This is to certify that following Medical Devices:

Product name	Product code	Basic UDI-DI	Intended purpose
HEALTHENTIA v3	-	54199801789HLTv3GW	Software intended for monitoring of non-vital parameters to support decision making and virtual coaching of patients during clinical trials or under a medical or wellbeing treatment context.

are manufactured and sold by:

INNOVATION SPRINT
 Clos Chapelle-aux-Champs 30 - bte 1.30.30
 1200 Brussels, Belgium
Single Registration Number: BE-MF-00000879

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.

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For INNOVATION SPRINT, made in Brussels, BELGIUM the 25th May 2021.

Dr. Sofoklis Kyriazakos
CEO