

EU Declaration of Conformity

Manufacturer	Hippo Dx (HippoCreates bv) Kempische Steenweg 303 bus 200 3500 Hasselt, Belgium
SRN#	BE-MF-000002106
Basic UDI DI	++G332SPATF2
Device Name / Trade Name	Skin Prick Automated Test (abbreviation: S.P.A.T.)
Intended Purpose	S.P.A.T. is intended to help healthcare professionals to perform the skin prick test. It supports the loading of allergens on the lancets and the application of the lancets to the skin. After a predefined incubation time, S.P.A.T. images the skin's reaction to the allergens and presents this information to a medical professional for further analysis.
Classification	Class IIa based on rule 6, 10, 11 and 12 of Annex VIII of Regulation (EU) 2017/745
Conformity Assessment Route:	Annex IX of Regulation (EU) 2017/745
Conformity Assessment Certificate:	Code: 21M00015CRT02 Date: 2024-12-03 Expiration date: 2029-12-02
Common Specifications	No common specifications are applicable.
EMDN Code	V9099 - VARIOUS DEVICES NOT INCLUDED IN OTHER CLASSES - OTHER
Notified Body	Kiwa Dare B.V. Vijzelmolenlaan 7 NL-3447 GX Woerden Netherlands Notified Body number : 1912

We hereby declare, under our own sole responsibility, that the device specified above meets the

- European Regulation 1907/2006 (Registration, Evaluation, Authorisation and Restriction of Chemicals, REACH)
- Essential Health and Safety Requirements of European Directive 2006/42/EC (Machinery Directive)
- European Directive 2011/65/EU (Restriction of Hazardous Substances, RoHS)
- European Directive 2012/19/EU (Waste Electrical and Electronic Equipment, WEEE)
- European Directive 2016/679 (General Data Privacy Regulation, GDPR)
- European Regulation 2017/745 (Medical Device Regulation, MDR)

This declaration is signed on behalf of the manufacturer, Hippocreates bv, and is issued at the address of the manufacturer.

Place, Date, Signature of CEO

DocuSigned by:


31-1-2025

Senne Gorris

CEO

Hasselt