European Commission

EUDAMED - European Database on Medical Devices

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UDI-DI: 18306110001166

Manufacturer details

Version 1 (Current) Last update date: 2022-04-17

Actor ID/SRN	CA-MF-000022852
Role	Manufacturer
Country	Canada
Organisation name	Technologies HumanWare Inc. [EN]
Address	1800, Michaud, J2C7G7, Drummondville
Telephone number	+15147793855
Email	lpmasse@humanware.com

Basic UDI-DI details

Version 1 (Current) Last update date: 2024-12-03

Applicable legislation	MDR (REGULATION (EU) 2017/745 on medical devices)
Basic UDI-DI / EUDAMED DI / Issuing entity	83061100001J9 / GS1
System/Procedure Pack which is a device in itself	System which is a device in itself
Authorised representative	NL-AR-000000111 - CEpartner4U - 13 Esdoornlaan 3951DB Maarn - Netherlands
Risk class	Class I
Implantable	No
Is the device a suture, staple, dental filling, dental brace, tooth crown, screw, wedge, plate, wire, pin, clip or connector?	No
Measuring function	No
Reusable surgical instrument	No
Active device	No
Device intended to administer and / or remove medicinal product	No
Device model	Braille device
Device name	Braille device

Tissues and cells

Presence of human tissues or cells or their derivatives	No

Presence of animal tissues or cells or their derivatives	No

Information on substances

Presence of a substance which, if used separately, may be considered to be a medicinal product	No
Presence of a substance which, if used separately, may be considered to be a medicinal product derived from human blood or human plasma	No

Certificates

There is no reference to this Basic UDI-DI in any certificate, because:

It does not require a certificate or
It requires only a certificate that does not reference the Basic UDI-DI (e.g. a QMS certificate) or
The required certificate(s) referencing this Basic UDI-DI is(are) not registered yet.

UDI-DI details

Version 1 (Current) Last update date: 2024-12-03

UDI-DI code / Issuing entity	18306110001166 / GS1
Status	On the EU market
UDI-DI from another entity (secondary)	-
Nomenclature code(s)	Y210999: Personal computer input and output peripheral equipment - other
Name/Trade name(s)	Monarch [EN]
Reference / Catalogue number	BNP480 - FGBR-1201
Direct marking DI	Yes
Quantity of device	1
Type of UDI-PI	Serial number
Additional Product description	Monarch Digital Tactile Display [EN]
Additional information url	-
Clinical sizes	-
Labelled as single use	No
Maximum number of reuses	-
Need for sterilisation before use	No
Device labelled as sterile	No
Containing Latex	No
Reprocessesed single use device	No
Intended purpose other than medical (Annex XVI)	No
Member state of the placing on the EU market of the device	France

Related Device

This device is not currently linked with any other devices.

Market distribution

Version 1 (Current) Last update date: 2024-12-03

Member State where the device is or is to be made available

Austria. (From - to -)

Belgium. (From - to -)

Bulgaria. (From - to -)

Croatia. (From - to -)

Cyprus. (From - to -)

Czechia. (From - to -)

Denmark. (From - to -)

Estonia. (From - to -)

Finland. (From - to -)

France. (From - to -)

Germany. (From - to -)

Greece. (From - to -)

Hungary. (From - to -)

Iceland. (From - to -)

Ireland. (From - to -)

Italy. (From - to -)

Latvia. (From - to -)

Liechtenstein. (From - to -)

Lithuania. (From - to -)

Luxembourg. (From - to -)

Malta. (From - to -)

Netherlands. (From - to -)

Norway. (From - to -)

Poland. (From - to -)

Portugal. (From - to -)

Romania. (From - to -)

Slovakia. (From - to -)

Slovenia. (From - to -)

Spain. (From - to -)

Sweden. (From - to -)

Türkiye. (From - to -)

Northern Ireland. (From - to -)