



Australian Government
Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Neomedix Systems Pty Ltd

for approval to supply

Neomedix Systems Pty Ltd - Minze Uroflowsystem: Homeflow and Hospiflow - Flowmeter, urine, reusable

ARTG Identifier	344570
ARTG Start Date	25/09/2020
Product Category	Medical Device Included Class Im
GMDN	36337
GMDN Term	Flowmeter, urine, reusable
Intended Purpose	Uroflow System, consisting of device and software app for measuring uroflows at patient's home or in a professional setting, recording a voiding diary and transferring results to the Urologist or other medical specialist for diagnosis.

Manufacturer Details	Address	Certificate number(s)
Minze NV	Offerandestraat 1 , Antwerpen , 2060 Belgium	DV-2020-MC-20123-1

ARTG Standard Conditions

The above Medical Device Included Class Im has been entered on the Register subject to the following conditions:

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Products Covered by This Entry

1. Minze Uroflowsystem: Homeflow and Hospiflow - Flowmeter, urine, reusable

Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration
PO Box 100, Woden ACT 2606 Australia
Phone: 1800 020 653
Email: info@tga.gov.au

ARTG Identifier: 344570
ARTG Start Date: 25/09/2020