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Geschäftsführer: Adam J. Mumford, Thomas Roßbach

USt.-Id.-Nr.: DE 157922203
Steuer-Nr. 204/134/90031

EC MEDICAL DEVICE DIRECTIVE
DECLARATION OF CONFORMITY

This declaration is made in accordance the essential requirements of the Council Directive 93/42/EEC.

The device is classified under Annex IX of the directive as follows:

- **Classification:** **Class IIa**
- **Term:** **Transient use**
- **Invasive :** **Invasive**
- **Rule:** **6**
- **Conformity Assessment Route:** **Annex II (excluding section 4)**
- **CE Certificate Number:** **GB19/964726**

GMDN Code and Definition **61578** - A sterile, hand-held manual instrument intended to be used for controlled skin puncture/cut to obtain a capillary blood specimen, performed by a healthcare provider (e.g., on a neonate) or a patient (e.g., a diabetic), typically at the fingertip or ear lobe. It includes a preloaded lancet tip, and has a manually powered mechanism (e.g., spring-loaded) which enables the tip to puncture to a predetermined depth and blood subsequently to be squeezed out of the puncture site. This is a single-use device.

Brand Names

Code	Product Name	Product Specification
AT1042	Unistik® 3 Comfort 28G (100)	28 Gauge – 1.8 mm Lancing Depth
AT1043	Unistik® 3 Comfort 28G (Bulk)	28 Gauge – 1.8 mm Lancing Depth
AT1044	Unistik® 3 Comfort 28G (200)	28 Gauge – 1.8 mm Lancing Depth
AT1045	Unistik® 3 Comfort 28G (50)	28 Gauge – 1.8 mm Lancing Depth
AT1047	Unistik® 3 Comfort 28G (50)	28 Gauge – 1.8 mm Lancing Depth
001653	Unistik® 3 Comfort 28G (100)	28 Gauge – 1.8 mm Lancing Depth
002027	Unistik® 3 Comfort 28G - Reimbursement (100)	28 Gauge – 1.8 mm Lancing Depth
002429	Unistik® 3 Comfort 28G (100)	28 Gauge – 1.8 mm Lancing Depth
AT1012	Unistik® 3 Extra 21G (100)	21 Gauge – 2.0 mm Lancing Depth
AT1013	Unistik® 3 Extra 21G (Bulk)	21 Gauge – 2.0 mm Lancing Depth
AT1014	Unistik® 3 Extra 21G (200)	21 Gauge – 2.0 mm Lancing Depth
AT1017	Unistik® 3 Extra 21G (50)	21 Gauge – 2.0 mm Lancing Depth
000026	Unistik® 3 Extra 21G (200)	21 Gauge – 2.0 mm Lancing Depth
000318	Unistik® 3 Extra 21G (50)	21 Gauge – 2.0 mm Lancing Depth

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002026	Unistik® 3 Extra 21G - Reimbursement (100)	21 Gauge – 2.0 mm Lancing Depth
002428	Unistik® 3 Extra 21G (100)	21 Gauge – 2.0 mm Lancing Depth
AT1022	Unistik® 3 Gentle 30G (100)	30 Gauge – 1.5 mm Lancing Depth
AT1024	Unistik® 3 Gentle 30G (200)	30 Gauge – 1.5 mm Lancing Depth
AT1025	Unistik® 3 Gentle 30G (50)	30 Gauge – 1.5 mm Lancing Depth
AT1027	Unistik® 3 Gentle 30G (50)	30 Gauge – 1.5 mm Lancing Depth
000105	Unistik® 3 Gentle 30G (50)	30 Gauge – 1.5 mm Lancing Depth
000106	Unistik® 3 Gentle 30G (100)	30 Gauge – 1.5 mm Lancing Depth
AT1052	Unistik® 3 Neonatal & Laboratory 18G (100)	18 Gauge – 1.8 mm Lancing Depth
AT1053	Unistik® 3 Neonatal & Laboratory 18G (Bulk)	18 Gauge – 1.8 mm Lancing Depth
AT1054	Unistik® 3 Neonatal & Laboratory 18G (200)	18 Gauge – 1.8 mm Lancing Depth
AT1057	Unistik® 3 Neonatal & Laboratory 18G (50)	18 Gauge – 1.8 mm Lancing Depth
001654	Unistik® 3 Neonatal & Laboratory 18G (100)	18 Gauge – 1.8 mm Lancing Depth
AT1002	Unistik® 3 Normal 23G (100)	23 Gauge – 1.8 mm Lancing Depth
AT1003	Unistik® 3 Normal 23G (Bulk)	23 Gauge – 1.8 mm Lancing Depth
AT1004	Unistik® 3 Normal 23G (200)	23 Gauge – 1.8 mm Lancing Depth
AT1007	Unistik® 3 Normal 23G (50)	23 Gauge – 1.8 mm Lancing Depth
AT1008	Unistik® 3 Normal 23G (50)	23 Gauge – 1.8 mm Lancing Depth
002025	Unistik® 3 Normal 23G - Reimbursement (100)	23 Gauge – 1.8 mm Lancing Depth
002430	Unistik® 3 Normal 23G (100)	23 Gauge – 1.8 mm Lancing Depth
AT1062	Unistik® 3 Dual 18G 100-count Carton	18 Gauge – 1.8 mm Lancing Depth
AT1064	Unistik® 3 Dual 18G 200-count Carton	18 Gauge – 1.8 mm Lancing Depth
AT1063	Unistik® 3 Dual 18G 1000-count Carton	18 Gauge – 1.8 mm Lancing Depth

The above device has been designed and manufactured within a quality system established and maintained by Owen Mumford Limited. The quality system, along with the relevant technical documentation is periodically reviewed by SGS Belgium NV; SGS House Noorderlaan 87 2030, Antwerp, Belgium. Notified Body number CE 1639. Owen Mumford Limited is solely responsible for this medical device.

Name: **Darren Mansell** Signature:

Job Title: **Regulatory Affairs Manager** Date: 05 MAR 2021

For Mr. J. Severn
Managing Director – Owen Mumford Ltd.

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