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Amtsgericht Aschaffenburg, HRB 9177
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
000361	Unistik® Touch 30G Lancet x 100	30 Gauge – 1.5 mm Lancing Depth
000362	Unistik® Touch 30G Lancet x 200	30 Gauge – 1.5 mm Lancing Depth
000363	Unistik® Touch 28G Lancet x 100	28 Gauge – 1.8 mm Lancing Depth
000364	Unistik® Touch 28G Lancet x 200	28 Gauge – 1.8 mm Lancing Depth
000365	Unistik® Touch 23G Lancet x 100	23 Gauge – 2.0 mm Lancing Depth
000366	Unistik® Touch 23G Lancet x 200	23 Gauge – 2.0 mm Lancing Depth
000367	Unistik® Touch 21G Lancet x 100	21 Gauge – 2.0 mm Lancing Depth
000368	Unistik® Touch 21G Lancet x 200	21 Gauge – 2.0 mm Lancing Depth
000874	Unistik® Touch 30G Lancet x 5	30 Gauge – 1.5 mm Lancing Depth
000875	Unistik® Touch 28G Lancet x 5	28 Gauge – 1.8 mm Lancing Depth
000876	Unistik® Touch 23G Lancet x 5	23 Gauge – 2.0 mm Lancing Depth
P002816	Unistik® Touch 16G Lancet	16 Gauge – 2.0 mm Lancing Depth
P002817	Unistik® Touch 16G Lancet	16 Gauge – 2.0 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.