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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

This information is confidential to Owen Mumford. The user is responsible for confirming use of the current approved revision prior to use.

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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