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Arbeitsgericht 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) |

GMDN Code and Definition 44127 - A device designed for the parenteral administration of a drug contained in a cartridge that forms part of, is attached to, or inserted into an autoinjector (drug pen injector). It is used by persons requiring regular, self-administrated dosages of insulin, hormones, or other pharmaceuticals. This device will typically be constructed as a double-ended, stainless steel needle of various sizes that is fixed to a threaded hub of plastic to which the drug pen injector is connected. This device is packaged in a sealed sterility barrier, and might include needle shielding safety features to reduce the risk of needle stick injury. This is a single-use device.

Brand Names

Code	Product Name	Product Specification
AN3527	Unifine Pentips - 12mm (Bulk)	12mm Needle Length, 29 Gauge
AN3529	Unifine Pentips - 12mm (100) / (5x100)	12mm Needle Length, 29 Gauge
AN3530	Unifine Pentips - 8mm (100) / (5x100)	8mm Needle Length, 31 Gauge
AN3537	Unifine Pentips - 8mm (Bulk)	8mm Needle Length, 31 Gauge
AN3540	Unifine Pentips - 4mm (100) / (5x100)	4mm Needle Length, 32 Gauge
AN3541	Unifine Pentips - 4mm 32G (100)	4mm Needle Length, 32 Gauge
AN3548	Unifine Pentips - 4mm 33G (Bulk)	4mm Needle Length, 33 Gauge
AN3550	Unifine Pentips - 5mm (100)	5mm Needle Length, 31 Gauge
AN3551	Unifine Pentips - 5mm (100)	5mm Needle Length, 31 Gauge
AN3557	Unifine Pentips - 5mm (Bulk)	5mm Needle Length, 31 Gauge
AN3590	Unifine Pentips - 6mm (100) / (5x100)	6mm Needle Length, 31 Gauge
AN3597	Unifine Pentips - 6mm (Bulk)	6mm Needle Length, 31 Gauge
001239	Unifine Pentips - 4mm 32G (100)	4mm Needle Length, 32 Gauge

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001241	Unifine Pentips - 5mm 31G (100)	5mm Needle Length, 31 Gauge
001242	Unifine Pentips - 6mm 31G (100)	6mm Needle Length, 31 Gauge
001243	Unifine Pentips - 8mm 31G (100)	8mm Needle Length, 31 Gauge
001244	Unifine Pentips - 12mm 29G (100)	12mm Needle Length, 29 Gauge
001448	Unifine Pentips - 33G 4mm (100)	4mm Needle Length, 33 Gauge
001449	Unifine Pentips - 33G 4mm (100)	4mm Needle Length, 33 Gauge
001450	Unifine Pentips - 33G 4mm (100)	4mm Needle Length, 33 Gauge
001537	Unifine Pentips - 33G 4mm (100)	4mm Needle Length, 33 Gauge
001538	Unifine Pentips - 33G 4mm (100)	4mm Needle Length, 33 Gauge
001558	Unifine Pentips - 33G 4mm (100)	4mm Needle Length, 33 Gauge
001684	Unifine Pentips - 5mm 30G (Bulk)	5mm Needle Length, 30 Gauge
001831	Unifine Pentips - 33G 4mm (5x100)	4mm Needle Length, 33 Gauge
001954	Unifine Pentips - 5mm 30G (100)	5mm Needle Length, 30 Gauge
001955	Unifine Pentips - 5mm 30G (100)	5mm Needle Length, 30 Gauge
001956	Unifine Pentips - 5mm 30G (100)	5mm Needle Length, 30 Gauge
002237	Unifine Pentips - 4mm 32G (Bulk)	4mm Needle Length, 32 Gauge
002287	Unifine Pentips - 5mm (100)	4mm Needle Length, 32 Gauge
002304	Unifine Pentips - 4mm 32G (100)	4mm Needle Length, 32 Gauge

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.

Name: **Darren Mansell**

Signature: 

Job Title: **Regulatory Affairs Manager**

Date: **01 DEC 2020**

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

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