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Amtsgericht Aschaffenburg, HRB 9177
Geschftsfhrer: Adam J. Mumford, Thomas Robach

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
AN3627	Unifine Pentips Plus - 12mm (Bulk)	12mm Needle Length, 29 Gauge
AN3629	Unifine Pentips Plus - 12mm (100)	12mm Needle Length, 29 Gauge
AN3630	Unifine Pentips Plus - 8mm (100)	8mm Needle Length, 31 Gauge
AN3637	Unifine Pentips Plus - 8mm (Bulk)	8mm Needle Length, 31 Gauge
AN3640	Unifine Pentips Plus - 4mm (100)	4mm Needle Length, 32 Gauge
AN3647	Unifine Pentips Plus - 4mm (Bulk)	4mm Needle Length, 32 Gauge
AN3648	Unifine Pentips Plus - 4mm 33G (Bulk)	4mm Needle Length, 33 Gauge
AN3650	Unifine Pentips Plus - 5mm (100)	5mm Needle Length, 31 Gauge
AN3657	Unifine Pentips Plus - 5mm (Bulk)	5mm Needle Length, 31 Gauge
AN3690	Unifine Pentips Plus - 6mm (100)	6mm Needle Length, 31 Gauge
AN3697	Unifine Pentips Plus - 6mm (Bulk)	6mm Needle Length, 31 Gauge
AN3729	Unifine Pentips Plus - 12mm (100)	12mm Needle Length, 29 Gauge

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AN3730	Unifine Pentips Plus - 8mm (100)	8mm Needle Length, 31 Gauge
AN3740	Unifine Pentips Plus - 4mm (100)	4mm Needle Length, 32 Gauge
AN3750	Unifine Pentips Plus - 5mm (100)	5mm Needle Length, 31 Gauge
AN3790	Unifine Pentips Plus - 6mm (100)	6mm Needle Length, 31 Gauge
001454	Unifine Pentips Plus - 33G 4mm (100)	4mm Needle Length, 33 Gauge
001455	Unifine Pentips Plus - 33G 4mm (100)	4mm Needle Length, 33 Gauge
001456	Unifine Pentips Plus - 33G 4mm (100)	4mm Needle Length, 33 Gauge
001540	Unifine Pentips Plus - 33G 4mm (100)	4mm Needle Length, 33 Gauge
001541	Unifine Pentips Plus - 33G 4mm (100)	4mm Needle Length, 33 Gauge
001542	Unifine Pentips Plus - 33G 4mm (100)	4mm Needle Length, 33 Gauge
001685	Unifine Pentips Plus - 5mm 30G (Bulk)	5mm Needle Length, 30 Gauge
001957	Unifine Pentips Plus - 5mm 30G (100)	5mm Needle Length, 30 Gauge
001958	Unifine Pentips Plus - 5mm 30G (100)	5mm Needle Length, 30 Gauge
001959	Unifine Pentips Plus - 5mm 30G (100)	5mm Needle Length, 30 Gauge
002286	Unifine Pentips Plus - 12mm (100)	12mm Needle Length, 29 Gauge
002298	Unifine Pentips Plus - 4mm 32G (Bulk)	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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