



Brook Hill, Woodstock, Oxfordshire
OX20 1TU, United Kingdom
T: +44 (0)1993 812021
F: +44 (0)1993 813466
E: info@owenmumford.co.uk
www.owenmumford.com

Authorised Representative

Owen Mumford GmbH
Alte Häge 1
63762 Großostheim
Telefon: 06026/9775-0
Telefax: 06026/9775-29
www.owen-mumford.de
E-Mail: info@owen-mumford.de

Sparkasse Miltenberg-Obernburg
IBAN: DE 28796500000500201983
SWIFT-BIC: BYLADEM1MIL

IK: 590 961 092

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) |

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

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

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.

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