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IK: 590 961 092

Amtsgericht Aschaffenburg, HRB 9177  
Geschaftsfuhrer: 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 with the Essential Requirements of the Council Directive 93/42/EEC.

The device is classified under Annex IX of the directive as follows:

- |                                       |                                       |
|---------------------------------------|---------------------------------------|
| • <b>Classification:</b>              | <b>Class IIa</b>                      |
| • <b>Term:</b>                        | <b>Transient Use</b>                  |
| • <b>Invasive :</b>                   | <b>Invasive</b>                       |
| • <b>Rule:</b>                        | <b>6</b>                              |
| • <b>Conformity Assessment Route:</b> | <b>Annex II (excluding section 4)</b> |

### 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	Specification
P004307A1	Unifine SafeControl 30G x 5mm	30G x 5mm
P004313A1	Unifine SafeControl 30G x 8mm	30G x 8mm
P004319A1	Unifine SafeControl 31G x 5mm	31G x 5mm
P004326A1	Unifine SafeControl 31G x 6mm	31G x 6mm
P004333A1	Unifine SafeControl 31G x 8mm	31G x 8mm
P004340A1	Unifine SafeControl 32G x 4mm	32G x 4mm
P004305A1	Unifine SafeControl 30G x 5mm	30G x 5mm
P004312A1	Unifine SafeControl 30G x 8mm	30G x 8mm
P004318A1	Unifine SafeControl 31G x 5mm	31G x 5mm
P004325A1	Unifine SafeControl 31G x 6mm	31G x 6mm
P004332A1	Unifine SafeControl 31G x 8mm	31G x 8mm
P004339A1	Unifine SafeControl 32G x 4mm	32G x 4mm
P004305A1	Unifine SafeControl 30G x 5mm	30G x 5mm
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P004339A1	Unifine SafeControl 32G x 4mm	32G x 4mm
P004389A1	Unifine SafeControl 32G x 4mm	32G x 4mm
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P004391A1	Unifine SafeControl 31G x 5mm	31G x 5mm
P004392A1	Unifine SafeControl 31G x 6mm	31G x 6mm
P004393A1	Unifine SafeControl 31G x 8mm	31G x 8mm
P004394A1	Unifine SafeControl 30G x 5mm	30G x 5mm
P004395A1	Unifine SafeControl 30G x 8mm	30G x 8mm
P004305A1	Unifine SafeControl 30G x 5mm	30G x 5mm
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P004318A1	Unifine SafeControl 32G x 4mm	32G x 4mm
P004019A1	Unifine SafeControl	5mm x 30G
P004023A1	Unifine SafeControl	8mm x 30G
P004021A1	Unifine SafeControl	5mm x 30G
P004025A1	Unifine SafeControl	8mm x 30G
P004022A1	Unifine SafeControl	5mm x 30G
P004026A1	Unifine SafeControl	8mm x 30G
P004020A1	Unifine SafeControl	5mm x 30G
P004024A1	Unifine SafeControl	8mm x 30G
P004041A1	Unifine SafeControl	5mm x 31G
P004045A1	Unifine SafeControl	6mm x 31G
P004049A1	Unifine SafeControl	8mm x 31G
P004043A1	Unifine SafeControl	5mm x 31G
P004047A1	Unifine SafeControl	6mm x 31G
P004051A1	Unifine SafeControl	8mm x 31G
P004044A1	Unifine SafeControl	5mm x 31G
P004048A1	Unifine SafeControl	6mm x 31G
P004052A1	Unifine SafeControl	8mm x 31G
P004042A1	Unifine SafeControl	5mm x 31G
P004046A1	Unifine SafeControl	6mm x 31G
P004050A1	Unifine SafeControl	8mm x 31G
P004037A1	Unifine SafeControl	4mm x 32G
P004039A1	Unifine SafeControl	4mm x 32G
P004040A1	Unifine SafeControl	4mm x 32G
P004038A1	Unifine SafeControl	4mm x 32G

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.

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Name: **Darren Mansell**

Job Title: **Regulatory Affairs Manager**

Signature:



Date:

31 AUG 2021

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