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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 with 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-administered 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
001333	Ateria SafeControl 8mm x 30G	8mm Needle Length, 30 Gauge
001334	Ateria SafeControl 5mm x 30G	5mm Needle Length, 30 Gauge
001340	Ateria SafeControl 8mm x 30G	8mm Needle Length, 30 Gauge
001341	Ateria SafeControl 5mm x 30G	5mm Needle Length, 30 Gauge
001869	Ateria SafeControl 8mm x 30G	8mm Needle Length, 30 Gauge
001870	Ateria SafeControl 30G 5mm	5mm Needle Length, 30 Gauge
002039	Ateria SafeControl 30G 5mm	5mm Needle Length, 30 Gauge
002040	Ateria SafeControl 30G 5mm	5mm Needle Length, 30 Gauge
002041	Ateria SafeControl 30G 5mm	5mm Needle Length, 30 Gauge
002042	Ateria SafeControl 30G 5mm	5mm Needle Length, 30 Gauge
002043	Ateria SafeControl 30G 5mm	5mm Needle Length, 30 Gauge
002044	Ateria SafeControl 30G 5mm	5mm Needle Length, 30 Gauge
002046	Ateria SafeControl 30G 8mm	8mm Needle Length, 30 Gauge

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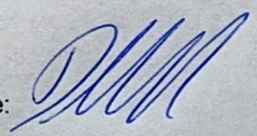
002047	Ateria SafeControl 30G 8mm	8mm Needle Length, 30 Gauge
002048	Ateria SafeControl 30G 8mm	8mm Needle Length, 30 Gauge
002049	Ateria SafeControl 30G 8mm	8mm Needle Length, 30 Gauge
002050	Ateria SafeControl 30G 8mm	8mm Needle Length, 30 Gauge
002051	Ateria SafeControl 30G 8mm	8mm Needle Length, 30 Gauge
002618	Ateria SafeControl 30G 5mm	5mm Needle Length, 30 Gauge
002619	Ateria SafeControl 30G 8mm	8mm Needle Length, 30 Gauge
P003559A1	Ateria SafeControl 31G 5mm bulk	5mm Needle Length, 31 Gauge
P003567A1	Ateria SafeControl 31G 6mm bulk	6mm Needle Length, 31 Gauge
P003575A1	Ateria SafeControl 31G 8mm bulk	8mm Needle Length, 31 Gauge
P003583A1	Ateria SafeControl 32G 4mm bulk	4mm Needle Length, 32 Gauge
P003552A1	Ateria SafeControl 31G 5mm CE (ROW) - Language Set 1A	5mm Needle Length, 31 Gauge
P003553A1	Ateria SafeControl 31G 5mm CE (ROW) - Language Set 1B	5mm Needle Length, 31 Gauge
P003554A1	Ateria SafeControl 31G 5mm CE (ROW) - Language Set 2A	5mm Needle Length, 31 Gauge
P003555A1	Ateria SafeControl 31G 5mm CE (ROW) - Language Set 2B	5mm Needle Length, 31 Gauge
P003556A1	Ateria SafeControl 31G 5mm CE (ROW) - Language Set 3A	5mm Needle Length, 31 Gauge
P003557A1	Ateria SafeControl 31G 5mm CE (ROW) - Language Set 3B	5mm Needle Length, 31 Gauge
P003558A1	Ateria SafeControl 31G 5mm CE (ROW) - Language Set 4 (Malaysian)	5mm Needle Length, 31 Gauge
P003560A1	Ateria SafeControl 31G 6mm CE (ROW) - Language Set 1A	6mm Needle Length, 31 Gauge
P003561A1	Ateria SafeControl 31G 6mm CE (ROW) - Language Set 1B	6mm Needle Length, 31 Gauge
P003562A1	Ateria SafeControl 31G 6mm CE (ROW) - Language Set 2A	6mm Needle Length, 31 Gauge
P003563A1	Ateria SafeControl 31G 6mm CE (ROW) - Language Set 2B	6mm Needle Length, 31 Gauge
P003564A1	Ateria SafeControl 31G 6mm CE (ROW) - Language Set 3A	6mm Needle Length, 31 Gauge
P003565A1	Ateria SafeControl 31G 6mm CE (ROW) - Language Set 3B	6mm Needle Length, 31 Gauge
P003566A1	Ateria SafeControl 31G 6mm CE (ROW) - Language Set 4 (Malaysian)	6mm Needle Length, 31 Gauge
P003568A1	Ateria SafeControl 31G 8mm CE (ROW) - Language Set 1A	8mm Needle Length, 31 Gauge
P003569A1	Ateria SafeControl 31G 8mm CE (ROW) - Language Set 1B	8mm Needle Length, 31 Gauge
P003570A1	Ateria SafeControl 31G 8mm CE (ROW) - Language Set 2A	8mm Needle Length, 31 Gauge
P003571A1	Ateria SafeControl 31G 8mm CE (ROW) - Language Set 2B	8mm Needle Length, 31 Gauge
P003572A1	Ateria SafeControl 31G 8mm CE (ROW) - Language Set 3A	8mm Needle Length, 31 Gauge
P003573A1	Ateria SafeControl 31G 8mm CE (ROW) - Language Set 3B	8mm Needle Length, 31 Gauge
P003574A1	Ateria SafeControl 31G 8mm CE (ROW) - Language Set 4 (Malaysian)	8mm Needle Length, 31 Gauge
P003576A1	Ateria SafeControl 32G 4mm CE (ROW) - Language Set 1A	4mm Needle Length, 32 Gauge

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P003577A1	Ateria SafeControl 32G 4mm CE (ROW) - Language Set 1B	4mm Needle Length, 32 Gauge
P003578A1	Ateria SafeControl 32G 4mm CE (ROW) - Language Set 2A	4mm Needle Length, 32 Gauge
P003579A1	Ateria SafeControl 32G 4mm CE (ROW) - Language Set 2B	4mm Needle Length, 32 Gauge
P003580A1	Ateria SafeControl 32G 4mm CE (ROW) - Language Set 3A	4mm Needle Length, 32 Gauge
P003581A1	Ateria SafeControl 32G 4mm CE (ROW) - Language Set 3B	4mm Needle Length, 32 Gauge
P003582A1	Ateria SafeControl 32G 4mm CE (ROW) - Language Set 4 (Malaysian)	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:

05 FEB 2021

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

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