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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 I**
- **Term:** **Transient Use**
- **Invasive:** **Non-invasive (contacts only intact skin)**
- **Rule:** **1**
- **Conformity Assessment Route:** **Annex VII and Annex II (excluding Section 4)***
*Annex II relates only to the aspects of manufacture concerned with securing and maintaining sterile conditions

GMDN Code and Definition **61582** - A sterile component of a pressure algometer intended to be loaded into an appropriate parent holder/pen for the assessment of a patient's sensitivity to pain (pain threshold) by application to the skin. It is a pointed tip which, when used in combination with the strain gauge of the parent device, will exert a known pressure. The device is typically used to evaluate the effects of pain after the use of anaesthesia/analgesics and/or during diagnosis or treatment of nerve injuries and neuropathies. This is a single-use device.

Brand Names

Code	Product Name
NT5405	Neurotips™ (100) / (100x100) / (5x100)

The above device has been designed and manufactured within a quality system established and maintained by Owen Mumford Limited.

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.