Invacare Regulatory Status and Strategy – May 2021

All Invacare EMEA Class I devices placed on the market are in conformity with the Medical Device Regulation (MDR) 2017/745. The CE declaration of conformity can be found on the Invacare website: **www.Invacare.eu**

Class IIa and IIb devices

To ensure a smooth transition, it is possible to place products in higher risk classes with a valid MDD 93/42/EEC certificate on the market until the end of the period indicated on the certificate (latest until 27 May 2024).

The following Class IIa and Class IIb devices are certified by the notified body SGS Belgium NV 1639, and meet the requirements of Directive 93/42/EEC.

- **Perfecto2V stationary oxygen concentrator**
- **Platinum 9 stationary oxygen concentrator**
- **Platinum Mobile portable oxygen concentrator**
- **HomeFill compressor**
- **HomeFill cylinder**
- **Paediatric Flow meter**

The certificates are valid until 15th of September 2023. A project plan is in place for the transition to MDR before the certificates becomes void.

Unique device identifier – UDI

UDI is a requirement to ensure traceability of devices. The Basic UDI-DI must be set up from 26th May 2021 and shall be stated in the Declaration of conformity.

Placing of the UDI carrier on the labels of the devices is not yet required but will become mandatory:

- **Class IIa and IIb devices: 26th May 2023**
- **Class I devices: 26th May 2025**

Until then, identification of our devices is guaranteed by serial or lot numbers and in the event of a Field Safety Corrective Action, we can trace the affected products in the market and inform our customers accordingly.

QMS

The Invacare Quality Management System is updated to comply with relevant MDR requirements. In particular the Technical documentation, including the Post Market Surveillance system, has been brought to a higher level, to ensure compliance with safety and performance requirements.

As part of the conformity assessment procedure all our devices are tested to harmonised standards to fulfil the MDR General safety and performance requirements.

Distributors obligations

To comply to MDR, distributors must meet certain requirements:

- **Ensure device traceability to customer or user**
- **Ensure that complaints and incidents are reported to Invacare**
- **Ensure that the devices are compliant: that the User manual is delivered with the device in the correct language and that a Declaration of Conformity for the device is available**
- **Ensure that storage and transport conditions comply with the conditions set by the manufacturer**

Transport, storage, maintenance, and service life

Information about any specific transport or storage conditions can be found in the User manuals on the Invacare website: **www.Invacare.eu**

The expected service life for Invacare devices is stated in the User manual and it applies when the device is used daily and in accordance with the safety instructions, maintenance intervals and correct use as stated in the manual.

Note that the effective service life can vary according to frequency and intensity of use.

EUDAMED

The European database EUDAMED consists of 6 interconnected modules. As the different modules are released Invacare will ensure that use of modules will be managed in a timely manner.

The Actors module is live, and Invacare has submitted application for actor's registration and is awaiting validation from Competent Authorities.

The next modules to be released are:

- **UDI/Device registration (plan Sep-21)**
- **Notified Bodies/ Certificates (plan Sep-21)**

Medical devices and BREXIT

The BREXIT places Great Britain as a third country and the new regulation states that an UK authorized representative needs to be appointed to be able to sell medical devices on the British market. Invacare Ltd has the mandate to act as UK representative for all Invacare sites and is registered in the MHRA database.

Additionally, all non-UK manufactured devices must be registered in the MHRA database. The deadline for registration is Sep 2021 for Class IIa and Class IIb devices and Jan 2022 for Class I devices. Invacare already initiated the registration process and the planned completion is Q2 2021.

Medical devices in Switzerland

Switzerland as a non-EU country needs to sign a Mutual recognition agreement, MRA, to be able to act under the MDR(EU) 2017/745. Until now this has not been done which places Switzerland as a third country with its own regulations for medical devices.

The CE-mark is still valid but to be able to place non-Swiss manufactured medical devices on the Swiss market a Swiss representative need to be appointed. The Contingency Medical Devices Ordinance (MedDO) provides transitional periods for the appointment of a Swiss representative, including corresponding labelling, according to risk classes:

Until 31 March 2022 for non-implantable class IIb devices and class IIa devices.

Until 31 July 2022 for Class I devices.

Invacare will appoint Invacare International GmbH located in Switzerland as the Swiss representative for all Invacare sites.

The registration process will be initiated as soon as Contingency MedDO is approved and the requirements are clear. This will ensure the availability and continuous market access for Invacare devices on the Swiss market.

Invacare is continuously monitoring regulatory changes and updates on all markets to ensure that devices and procedures are compliant with required regulations.

Tel: +41 61 487 70 70
compliance@invacare.com
www.invacare.eu.com

Invacare International GmbH
Benkenstrasse 260
4108 Witterswil
Switzerland

Yes, you can.