

# Notice: New Service Lifetime Regulations, effective January 1, 2021

Dear valued customer,

As a global medical device manufacturer, Ottobock is legally obligated to comply with The European Union Medical Device Regulation of 2017 (**EU MDR 2017/745**). Effective January 1, 2021, Ottobock will adhere to **service lifetime** standards to ensure our compliance with EU MDR 2017/745. This will directly impact the amount of time Ottobock can provide service or repair on our products. Additionally, Ottobock is required to and will maintain strict Post Market Surveillance for any of its products placed into the market, which now includes Class 1 medical devices.

A product's **Service Lifetime** is determined by the design and development of the product, and is the amount of time that the manufacturer determines the product to be "serviceable" and for which it can function safely and effectively.

## What does this mean?

In practice, this means that **Ottobock can provide no further maintenance or repair services once the product has reached its specified End of Service (EOS) lifetime. Ottobock will no longer accept maintenance and repair orders for products that have reached EOS.** Ottobock takes these obligations very seriously as they concern the safety and performance of our products.

## FAQs

- New regulation is effective January 1, 2021
- Applies to all mechanical and mechatronic components in the field of prosthetics and custom orthotics, and to all their accessories
- **Applies retroactively to all sold products on the market**
- Excludes repairs that are covered by warranty claims on previous repair work
- Product Service Lifetime clock starts on the day of delivery by Ottobock to the O&P professional as documented in the delivery note
- Service Lifetimes vary by product category (please visit our website for an appendix of all product categories and associated lifetimes)

**Please note that a products Service Lifetime may differ from its Warranty period.** However, Service Lifetimes will always exceed Warranty periods to ensure our ability to repair and maintain products while under warranty. Service Lifetimes and Warranty Periods for all Ottobock products can be found by visiting our website.

We kindly request that you consider the impact of the new statutory requirements detailed in this MDR. There will be instances where a patient will need to pursue a new fitting, and their device considered irreparably worn or broken, as we can no longer provide service or maintenance once it reaches its designated End of Service Lifetime.

We are confident that the new MDR was passed to help ensure the long-term safety and benefit of those who use prosthetic or custom orthotic products. Our mission is to help people maintain or regain their freedom of movement, and we continually strive to meet that mission with your support.

Thank you for your understanding.

Sincerely,

**Oliver Jakobi**  
Chief Sales Officer (CSO)

**Arne Jörn**  
Chief Operating Officer (COO)



Quality for life

The following is a list of Ottobock mechanical hip joints and their stated Service Lifetime<sup>1</sup>.

#### Hip Joints (mechanical)

Article No.	Product Name	Service Lifetime
7E4	Modular monocentric hip joint	3 years
7E5=L	Modular monocentric hip joint	3 years
7E5=R	Modular monocentric hip joint	3 years
7E7	Modular monocentric hip joint with internal extension assist	3 years
7E9	Monocentric hip joint with hydraulic control unit	3 years
7E10=L	Helix3D hip joint	3 years
7E10=R	Helix3D hip joint	3 years

<sup>1</sup>Service Lifetimes referenced in this document apply to the United States and Canada. Local regulations may impact Service Lifetimes in other locations.