

# New service of 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)

The following is a list of Ottobock mechanical knee joints and their stated Service Lifetime.

## Knee Joints (mechanical)

Article No.	Product Name	Service Lifetime
3R15	Modular monocentric knee joint with friction brake, with extension assist and protective sleeve	5 years
3R17	Modular single axis knee joint, with lock and extension assist	5 years
3R20	Ottobock habermann modular polycentric knee joint with internal extension assist	5 years
3R21	Modular knee joint for disarticulation, polycentric, with mechanical extension assist	5 years
3R23	Modular knee joint for knee disarticulation, polycentric, with manual lock	5 years
3R30	Modular knee joint for disarticulation, polycentric, with mechanical extension assist	5 years
3R31	Prosedo	5 years
3R31=ST	Prosedo	5 years
3R32	Modular knee joint for knee disarticulation, polycentric, with manual lock	5 years
3R33	Modular single axis knee joint, with lock and extension assist	5 years
3R36	Ottobock habermann modular polycentric knee joint with internal extension assist	5 years
3R40	Modular lightweight single axis knee joint with lock	5 years
3R46	Modular knee joint for disarticulation, polycentric, with hydraulic swing phase control	5 years
3R49	Modular monocentric knee joint with friction brake, with extension assist and protective sleeve	5 years
3R55	Modular polycentric knee joint with hydraulic swing phase control	5 years
3R60	Modular polycentric EBS knee joint with hydraulic swing phase control	5 years
3R60=HD	Modular polycentric EBS knee joint with hydraulic swing phase control	5 years
3R60=KD	Modular polycentric EBS knee joint with hydraulic swing phase control	5 years
3R60=ST	Modular polycentric EBS knee joint with hydraulic swing phase control	5 years
3R60=VC	3R60 Vacuum	5 years
3R60-PRO	Modular EBSspro polycentric knee joint with hydraulic swing phase control	5 years
3R60-PRO=HD	Modular EBSspro polycentric knee joint with hydraulic swing phase control	5 years
3R60-PRO=KD	Modular EBSspro polycentric knee joint with hydraulic swing phase control	5 years
3R60-PRO=ST	Modular EBSspro polycentric knee joint with hydraulic swing phase control	5 years
3R62	Pheon	5 years
3R62=1	Pheon	5 years
3R62=1-KD	Pheon	5 years
3R62=1-ST	Pheon	5 years
3R62=KD	Pheon	5 years
3R62=ST	Pheon	5 years
3R78	Polycentric knee joint with pneumatic swing phase control	5 years
3R78=KD	Polycentric knee joint with pneumatic swing phase control	5 years
3R78=ST	Polycentric knee joint with pneumatic swing phase control	5 years
3R80	Modular monocentric knee joint with rotary hydraulics	5 years
3R80=ST	Modular monocentric knee joint with rotary hydraulics	5 years
3R90	Modular knee joint with friction brake, monocentric with mechanical extension assist	5 years
3R92	Modular knee joint with friction brake, monocentric with pneumatic swing phase control	5 years
3R93	Modular friction brake knee joint with lock	5 years
3R95	Modular knee joint, monocentric, with hydraulic swing phase control	5 years
3R95=1	Modular knee joint, monocentric, with hydraulic swing phase control	5 years
3R106	Modular polycentric knee joint with pneumatic swing phase control	5 years
3R106=HD	Modular polycentric knee joint with pneumatic swing phase control	5 years
3R106=KD	Modular polycentric knee joint with pneumatic swing phase control	5 years
3R106=ST	Modular polycentric knee joint with pneumatic swing phase control	5 years
3R106-PRO	Modular polycentric knee joint with servo-pneumatic swing phase control	5 years
3R106-PRO=KD	Modular polycentric knee joint with servo-pneumatic swing phase control	5 years
3R106-PRO=ST	Modular polycentric knee joint with servo-pneumatic swing phase control	5 years
3WR95	Aqua knee	5 years