



Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions for certain medical devices in particular with respect to:

- the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) and
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	REGANEMED GmbH
Manufacturer address and contact details	Klinger Strasse No:26 Frankfurt am Main Germany

Notified body name	UDEM
Notified body number	2292
Medical Device and Directive Certificate number to which this confirmation is made	CHONDROPLUS M.2020.106.13770 <i>EC Declaration of Conformity Full Quality Assurance System</i> M.2020.106.13770-1 <i>EC Design-Examination Certificate</i>
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	27/05/2024
End date of extended validity/transition period	31/12/2027

We, as the manufacturer declare under our sole responsibility:

- for the above listed Directive Certificate the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met,
- the listed Device and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR (as amended by (EU) 2023/607), for continued placing on the market and putting into service



namely by fulfilling the following conditions:

- **Directive Certificates** as listed above
 - Directive Certificates covering the listed device were issued after 25 May 2017, were valid on 26 May 2021 and have not been withdrawn afterwards,
 - Expired after 20 March 2023,
 - Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment have been made submitted by us to a notified body no later than 26 May 2024 for the devices listed and signed written agreement is in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

- **Quality Management System (QMS)**
 - A QMS in accordance with Article 10(9) MDR is in place

- **Device as listed above**
 - The device continue to comply with the MDD,
 - There are no significant changes in the design and intended purpose,
 - The device do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Date: 27/05/2024

Reganemed GmbH
Klinger Strasse No:26
Frankfurt am Main Germany

Dr.Klaus Müller
Geschäftsführer