Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulation (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.

Manufacturer name	Königsee Implantate GmbH
Manufacturer address and contact details	Königsee Implantate GmbH Am Sand 4 07426 Allendorf Germany
Single Registration Number (SRN)	DE-MF-000010329

Notified body name	TÜV Rheinland LGA Products GmbH
Notified body number	0197
Directive Certificate number to which this confirmation is made	HD 60148793 0001
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	2024-05-26
End date of extended validity/transition period	2028-12-31

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 and the listed devices in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service, namely by fulfilling the following conditions:

➢ **Directive Certificate** as listed above

- Directive Certificate covering the listed devices were issued after 25 May 2017, was valid on 26 May 2021 and have not been withdrawn afterwards.

☒ Expired after 20 March 2023:

☒ Formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been submitted by us to a notified body no later than 26 May 2024 for the devices listed in the attached schedule or their substitutes and signed written agreement is be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

➢ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

☒ Formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been submitted by us to a notified body no later than 26 May 2024 for the devices listed in the attached schedule or their substitutes and signed written agreements is be 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.

➢ **Devices as listed in the attached schedule**

- The devices continue to comply with the MDD.
- There are no significant changes in the design and intended purpose.
- The devices 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.

Signed for and on behalf of the manufacturer:

Allendorf, 28.05.2024

Place, Date

Königsee Implantate GmbH

Manufacturer's Declaration
(EU) 2023/607

Königsee Implantate

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the devices	Directive Certificate number to which this confirmation is made	Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	Notified Body name and number that issued the Directive Certificate	Notified Body name and number where the MDR application was lodged / contract signed	End date of extended validity / transition period	Substitute Devices
Orthopaedic fixation plate	DE-MF-000010329	2024-05-26	TÜV Rheinland LGA Products GmbH #0197	TÜV Rheinland LGA Products GmbH #0197	2028-12-31	Not applicable
Orthopaedic bone screw	DE-MF-000010329	2024-05-26	TÜV Rheinland LGA Products GmbH #0197	TÜV Rheinland LGA Products GmbH #0197	2028-12-31	Not applicable
Orthopaedic bone pin	DE-MF-000010329	2024-05-26	TÜV Rheinland LGA Products GmbH #0197	TÜV Rheinland LGA Products GmbH #0197	2028-12-31	Not applicable
Orthopaedic bone wire	DE-MF-000010329	2024-05-26	TÜV Rheinland LGA Products GmbH #0197	TÜV Rheinland LGA Products GmbH #0197	2028-12-31	Not applicable
Bone staple	DE-MF-000010329	2024-05-26	TÜV Rheinland LGA Products GmbH #0197	TÜV Rheinland LGA Products GmbH #0197	2028-12-31	Not applicable
Orthopaedic bone washer	DE-MF-000010329	2024-05-26	TÜV Rheinland LGA Products GmbH #0197	TÜV Rheinland LGA Products GmbH #0197	2028-12-31	Not applicable
Hip internal fixation system	DE-MF-000010329	2024-05-26	TÜV Rheinland LGA Products GmbH #0197	TÜV Rheinland LGA Products GmbH #0197	2028-12-31	Not applicable
Interlocking nail	DE-MF-000010329	2024-05-26	TÜV Rheinland LGA Products GmbH #0197	TÜV Rheinland LGA Products GmbH #0197	2028-12-31	Not applicable
Cerclage wire, cable	DE-MF-000010329	2024-05-26	TÜV Rheinland LGA Products GmbH #0197	TÜV Rheinland LGA Products GmbH #0197	2028-12-31	Not applicable
Orthopaedic instrument	DE-MF-000010329	2024-05-26	TÜV Rheinland LGA Products GmbH #0197	TÜV Rheinland LGA Products GmbH #0197	2028-12-31	Not applicable
Orthopaedic instrument with measuring function	DE-MF-000010329	2024-05-26	TÜV Rheinland LGA Products GmbH #0197	TÜV Rheinland LGA Products GmbH #0197	2028-12-31	Not applicable