Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic 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	CONDOR MedTec GmbH
Manufacturer address	Dr.-Krismann-Straße 15 33154 Salzkotten Germany
contact details	Ira Fecke-Schulte PRRC ira.fecke-schulte@condor-group.de
Single Registration Number (SRN)	DE-MF-000012962

Notified body name	TÜV NORD CERT GmbH
Notified body number	CE 0044
Directive Certificate number(s) to which this confirmation is made	44 232 117867
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	2023-12-21
End date of extended validity/transition period	2028-12-31
Medical Devices	CONDOR® GoldLine Surgical retractor system

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 **device(s)** on the first page 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Certificate covering the listed device(s) was issued after 25 May 2017, was valid on 26 May 2021 and have not been withdrawn afterwards.
- Directive Certificate 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 already been made by us to our notified body TÜV NORD CERT. A signed written agreement is already in place in accordance with Section 4.3, second subparagraph of Annex VII MDR. See Conformation Letter Reference No: 8003060713.

➢ **Quality Management System (QMS)**

- A QMS in accordance with Article 10(9) MDR is in place.

➢ **Device(s) as listed on the first page**

- The device(s) continue to comply with MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) 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:

CONDOR MedTec GmbH

Salzkotten, 21st December 2023

Ira Fecke-Schulte
PRRC
ira.fecke-schulte@condor-group.de

I. Fecke-Schulte
(Signature)