EU Certificate

Quality Management System
REGULATION (EU) 2017/745 on Medical Devices
Annex IX Chapter I, Section 2 and 3 and Chapter III

Registration No.:	HZ 2185282-1
Manufacturer:	B.J.ZH.F.Panther Medical Equipment Co., Ltd. Floor 3, Building 1, 28 Huoju Street, Changping Science and Technology Park, Changping District, 102200 Beijing, P.R. China
EUDAMED Single Registration No.:	CN-MF-000018084
Products:	Products of class IIa: H02030104 - SINGLE PATIENT STRAIGHT LINEAR STAPLERS FOR VIDEOSURGERY H02020101 - STRAIGHT LINEAR STAPLERS FOR OPEN SURGERY Products of class IIb: H02030106 - LINEAR STAPLERS FOR VIDEOSURGERY LINEAR STAPLER CARTRIDGES FOR VIDEOSURGERY H02020103 - LINEAR STAPLERS, OPEN SURGERY SINGLE-PATIENT LINEAR SUTURE CARTDRIGES FOR OPEN SURGERY

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled.
If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.:	190141886-120
Effective date:	2024-04-18
Expiry date:	2029-04-17
Issue date:	2024-04-18

Jing Zhang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

This certificate can be validated on https://www.certipedia.com

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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Authorized representative(s):	OBELIS S.A Boulevard Général Wahis, 53 1030 Brussels, Belgium

Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2024-04-18

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