

## Declaration Confirming Conditions for EU MDR Extension per Regulation 2023/607 are Fulfilled

To Whom it may concern,

GANSHORN declares its legacy devices are covered by the transitional period stated in Regulation (EU) 2023/607, amending Regulations (EU) 2017/745. GANSHORN's certified is issued by TÜV SÜD in accordance with Council Directives 93/42/ECC, was still valid on 26 May 2021, and has not been withdrawn afterwards. GANSHORN's EC Certificate remains valid after the expiry date of the certification until December 31, 2028 set by EU MDR Amendment 2023/607. GANSHORN has fulfilled all conditions required to continue to place medical devices in the market.

### **Legal manufacturer:**

GANSHORN Medizin Electronic GmbH  
Industriestrasse 6-8, 97618 Niederlauer, Germany  
SRN: DE-MF-000006566

### **Notified Body:**

TÜV SÜD Product Service GmbH  
Ridlerstrasse 65, 80339 München, Germany  
NB ID: 0123

**Certificate Number:** G1 073169 0005 Rev.01

**End Date of Transitional Period:** 31 December 2028

### **Device Classification:** IIa

#### **Devices Covered by Extension:**

- Powercube+ Series (Powercube Body+ / Powercube Diffusion+),
- LFX,
- Provo.X,
- PowerCube Ergo,
- ScoutTube

### **Conditions laid down in EU (MDR) 2017/745, Art. 120(2), (3a (b)) as amended by regulation 2023/607.**

- a. GANSHORN's medical device continue to comply with Council Directive 93/42/EEC;
- b. There are no significant changes in the design and intended purpose of GANSHORN's medical devices;
- c. GANSHORN's medical devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health;
- d. GANSHORN Medizin Electronic GmbH has put in place a quality management system in accordance with Art. 10(9);
- e. GANSHORN has lodged a formal application with TÜV SÜD covering all GANSHORN's medical devices. GANSHORN and TÜV SÜD have signed a written agreement in accordance with Regulation 2023/607.



Sincerely,  
2023-11-23

  
Dr. Stefan Ponto  
Co-Chief Executive Officer

  
Sirimanee Chatrojjanasakul  
Head of Quality Management & Regulatory Affairs