



MedPath GmbH, Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany

MedPath GmbH

Mies-van-der-Rohe-Strasse 8,
80807 Munich, Germany

To whom it may concern

Telefon: +49(0)89 189174474
Telefax: +49(0)89 5485 8884
E-Mail: info@medpath.pro

Munich, 03.07.2023

Confirmation of Validity of CE Certificate No. G2S 18 03 03804 002 to 31.12.2028

As the responsible EU Authorized Representative for *Suzhou Acmed Import & Export Co., Ltd.* under MDR EU 2017/745 MDR, *MedPath GmbH* herewith confirms that the device(s) in attachment 1 of this letter covered by the above-mentioned certificate fulfill(s) the requirements as defined in Regulation (EU) 2023/607. The above-mentioned certificate can be considered as valid until 31.12.2028, when *Suzhou Acmed Import & Export Co., Ltd.* continues to comply with the relevant requirements in Regulation (EU) 2023/607.

The confirmation was made taking into account following aspects:

- ☞ Regulation (EU) 2023/607 extends validity of CE certificate under EC 93/42/EC, considering limited capacity of MDR Notified Bodies (article 1.1.a)).
- ☞ Important condition of this extension is that the CE certificate was still valid on 20.03.2023. Furthermore, the manufacturer shall submit MDR certification application for these devices to a MDR Notified Body by no later than 26.05.2024, and shall sign MDR certification agreement with the Body by no later than 26.09.2024 (article 3c(e)).
- ☞ Other requirements for this extension include e.g.: the device(s) continue to comply with MDD (article 3c(a)); there are no significant changes in the design and intended purpose (article 3c(b)); devices do not present an unacceptable risk to the health or safety (article 3c(c)); the manufacturer has put in place a quality management system in accordance with MDR (article 3c(d)); a Notified Body is still performing surveillance activity (article 3f).
- ☞ The manufacturer has provided *MedPath GmbH* with the appropriate evidence and declaration of conformity demonstrating that the relevant requirements in Regulation (EU) 2023/607 have been fulfilled by now.

For any questions, please feel free to contact us in written form.

MedPath GmbH
Mies-van-der-Rohe-Strasse 8 · D-80807 München
Tel.089-189174474 · Fax 089-54858884

MedPath GmbH



Attachment 1 – Products List

Gauze Sponges without X-ray Detectable Thread,
Non-woven Sponges,
Sterile First-aid Dressing Bandage,
Sterile Wound Plasters (Sterile Plaster Strips),
First-Aid Kits,
Disposable Sterile Drapes,
Medical Dressing Kits,
Surgical Gown,
Rectal Tubes,
Urine Bags,
Vaginal Speculums,
Ostomy Bags,
Sterile Pad (Alcohol Pad)

MedPath GmbH
Mies-van-der-Rohe-Strasse 8 · D-80807 München
Tel. 089-189174474 · Fax 089-54858884