Certificate of Verification

Medical Device Safety Service CH GmbH (MDSS CH)
hereby declares that an Authorized Representative's Mandate according to the Swiss Medical Device Ordinance (MedDO) is in place and that the following tasks have been carried out in accordance with the requirements of the MedDO in conjunction with the MDR 2017/745 (MDR) on behalf of the Manufacturer:

WR Medical Electronics Co.
1700 Gervais Avenue
Maplewood, MN 55109
USA

MDSS CH verified that the declaration of conformity and technical documentation according to the MDR 2017/745 or MDD 93/42/EEC, as indicated on the attached table, have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer;

MDSS CH keeps available a copy of the technical documentation, the declaration of conformity and, if applicable, a copy of any relevant certificate, including any amendments and supplements at the disposal of competent authorities for the period referred to in MDR Article 10.8 in conjunction with MDR Article 11.3 point b;

MDSS CH complied with the registration obligations laid down in MedDO Article 55 ("CHRN") and verified that the Manufacturer has complied with the registration obligations (MedDO Article 55 in conjunction with MDR Article 11.3 point c).

Details of the device(s) covered by the Certificate are listed hereafter.

Issued: 2023-04-12

This Certificate is valid without signature.and can be traced within MDSS CH' electronic system.

Certificate No.: 591456

This certificate is subject to the following terms and conditions:
It is only valid for the device(s) listed hereafter;
It is not an approval for the CE marking/conformity marking;
The Manufacturer shall inform MDSS CH of any significant change(s) to the device(s) listed hereafter and MDSS CH will verify the change(s) and determine if a renewed certificate has to be issued;
The Manufacturer is liable for damages caused by a defect in his product(s). The Manufacturer in addition confirms that the requirements of Article 10.16 of the MDR are fulfilled.
This Certificate of Verification is valid for 5 years or until expiry of the EU Declaration of Conformity or the Certificate issued by a notified body/conformity assessment body if applicable, whichever comes first.
Devices falling under Article 120 (3) of the MDR 2017/745 are covered as long as Article 120 (3) applies to them.

Devices as per MDR 2017/745						
Technical File	**Generic Device Description/ Trade Name**	**Nomenclature system and code**	**Risk Class**	**Declaration of Conformity, signature date**	**Notified Body / Conformity Assessment Body ID No. / Cert. No.**	**Notified Body / Conformity Assessment Body Cert. valid until YYYY-MM-DD**
None						

Devices not compliant to MDR 2017/745, but compliant to MDD 93/42/EEC and covered by MDR Article 120 (3)

The devices are covered by this Certificate of Verification as long as Article 120 (3) applies to them. Examples leading to the non-applicability of this Article are the expiry of the Certificate(s) issued by a Notified Body in accordance with MDD 93/42/EEC or significant changes in the design and intended purpose. The applicability of MDR Article 120 (3) is evaluated by and under responsibility of the Manufacturer. MDSS has to be informed once that Article is no longer applicable.

Technical File	**Generic Device Description/ Trade Name**	**Nomenclature system and code**	**Risk Class**	**Declaration of Conformity, signature date**	**Notified Body ID No. / Cert. No.**	**Notified Body / Conformity Assessment Body Cert. valid until YYYY-MM-DD**
RA-1 Revision 12	Therabath® Professional Grade Paraffin Bath (TB7 and TB10)	35232	IIa	Declaration of Conformity Therabath Rev 5 Signed February 13, 2023	0413 / 41314493-02	2023-10-17