CE

EU Declaration of Conformity

The following description for the medical device,

Device information	Description
EU Single Registration Number (SRN)	**TW-MF-000011689**
Registered trade name and address	Valentine International Ltd. 8th Fl., No. 149, Sec. 2, Ta Tung Rd., Hsichih District, New Taipei City 221424, Taiwan R.O.C. Tel: +886-2-8692-66662
EU Single Registration Number (SRN)	**DE-AR-000045617**
Authorized representative	KOMAS Medical Technology GmbH Sternstraße, 67 40479 Düsseldorf, Germany.
Common device name	Wrist orthosis
UMDNS Code	12102, Immobilizers, Wrist 17911, Orthoses, Wrist
GMDN Code	Wrist immobilizer, reusable Wrist orthosis
Basic UDI-DI	4719879702071
Risk class of the device	Class I
Common Specification (CS) References	Upper-Extremity Supports, Wrist immobilizer, Wrist Support, Wrist Braces #38006, 38007, 38009, 38010, 38011, 43102-04, 12090, 12079, 14031, 14032, 30125, 13570/7, 13570/11, 30007, 30010, 23329, 36001, 37001, 38002, 38003, 38004, 38005, 27027, 27208, 27307, 27308, 27407, 27408, 27507, 27508, 27602, 27603, 27604, 27605, 28207, 28208, 28307, 28308, 28407, 28408, 28507, 28508, 29107, 29108, 29207, 29208, 29307, 29408, 29407, 29408, 29507, 29508, 33207, 33208, 33307, 3308, 33407, 33408, 33507, 33508
Intended purpose (GMDN definition)	A rigid external support designed to temporarily render the wrist immovable as therapy for non-displaced fractures, strains, sprains, and muscle injuries of the wrist. The rigid support typically includes a wrap which may be held in place with a fastener such as Velcro; it is available in a variety of sizes. This is a reusable device. A prefabricated (non-customized) externally applied orthopaedic appliance or apparatus designed to support, align, prevent, or correct deformities/injuries or to improve function of the wrist. This is a reusable device.

Issued date: May 19, 2022
Version: V2.0

Conformity assessment procedure performed and identification of the certificates issued by notified body, if applicable	Quality management System ISO 13485:2016 By DNV GL Presafe AS (Identification Number: 2460)
Name and identification number of the notified body, if applicable	Certificate Number: 217412-2017-AQ-RGC-NA-PS

That is covered by the present declaration is in conformity with the EU Medical Device **Regulation 2017/745/EU**. The device is in conformity with conformity assessment procedure for **Class I devices** that should be carried out, as a rule, under the sole responsibility for the above such devices. The class I devices, other than custom-made or investigational devices, shall declare the conformity of their products by issuing an EU declaration of conformity referred to in Article 19 "EC declaration of conformity" after drawing up the technical documentation set out in Annexes II and III of the **Regulation**.

For the evaluation regarding Class I device (Risk class in accordance with the Rule 1 set out in Annex VIII of the Regulation), the following harmonized standards are applied.

- EN ISO13485:2016 Medical Devices -Quality management systems – Requirements for regulatory purposes.
- EN ISO14971:2019 Medical Devices – Application of Risk Management
- EN ISO 15223-1: 2016 Medical Devices – Symbols to be used with medical devices, labels, labelling and information to be supplied – Part 1: General requirements
- EN 62366-1:2015 Medical devices Part 1 – Application of usability engineering to medical devices.

The following Union authorized representative is stated to the declaration:
KOMAS Medical Technology GmbH
Sternstraße, 67 40479 Düsseldorf, Germany.
(Company name /Registered place of business)

The following person is exclusively responsible for the compliance of declaration:
Valentine International limited
8th Fl., No. 149, Sec. 2, Ta Tung Rd., Hsichih District, New Taipei City 221424, Taiwan R.O.C.
(Manufacturer's name /Registered address)

Yuhsin Chiu/ Managing Director	Yuhsin Chiu	Sep. 01, 2024
(Name/Function)	(Legal Signature)	(Date of issue)