



Declaration of Conformity

To whom it may concern,

As you may be aware, the EU Regulation 2023/607 extends the MDR transitional period, which results in the extended validity of CE certificates for legacy devices. Consequently, TaeWoong Medical's implantable stents may continue to be placed on the market until December 31st, 2027, and Optimos™ Guidewire until December 31st, 2028 under the following conditions as defined in the amended article 120(3c):

a) Devices continue to comply with Directive 93/42/EEC:

TaeWoong Medical will continue to comply with Directive 93/42/EEC until December 31st, 2028.

b) There are no significant changes in the design and intended purpose:

Devices approved under the Directive 93/42/EEC will undergo neither significant change nor change in intended purpose. Please note that once a device will be approved under MDR 2017/745, it will no longer be approved under Directive 93/42/EEC.

c) 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 or public health:

TaeWoong Medical's Niti-S & ComVi stents and Optimos™ Endoscopic accessories have been CE-marked based on clinical safety and clinical performance. Additionally, a benefit/risk assessment has been performed in order to ensure that the benefits of the devices are higher than the risks. Consequently, the devices do not represent any unacceptable risks.

d) No later than May 26th 2024, the manufacturer has put in place a quality management system in accordance with the Article 10(9);

TaeWoong Medical has passed the Quality Management System audit based on MDR EU 2017/745 and is currently awaiting the issue of the certificate.

e) No later than May 26th 2024, the manufacturer or the authorized representative has lodged a formal application with a notified body in accordance with Section 4.3, first paragraph of Annex VII for conformity assessment, and no later than September 26th, 2024 the notified body and the manufacturer have signed a written agreement in accordance with Section 4.3, second paragraph, of Annex VII

TaeWoong Medical has signed a contract with its notified body SGS for the technical documentation review of the stents and the Optimos™ accessories (guidewire and cystotome) for MDR review.

Additionally, in accordance with the Extension of the MDR Transitional period and removal of the 'Sell Off' periods (Q&A on practical aspects related to the implementation of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices) (Rev.1) published on July 2023. If the manufacturer does not lodge an application for conformity assessment by 26 May 2024, the transition period will end on 26 May 2024. (Part A, section 3).

Consequently, TaeWoong Medical's devices that are not being submitted for MDR review will be marketed only until May 26th, 2024.

TaeWoong Medical's transition period is therefore from May 26th, 2024 to December 31st, 2027 for stents and up to December 31st, 2028 for Optimos™ Endoscopic accessories. Please note that once a device is approved under MDR EU 2017/745, it is not anymore approved under MDD 93/42/EEC.

Taewoong Medical is providing the following attachments:

Attachment 1. List of devices that will be deleted after May 26th, 2024

Attachment 2. List of Legacy Devices

Date of Issue: May 20th, 2024



Signature:

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