

SMI A.G.
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St.Vith, 18/01/2018

DECLARATION: CERTIFICATION TRANSFER

To whom it may concern

Dear,

This is to certify that SMI AG is currently in the process to transfer all ISO & CE certifications to the notified body LRQA (Lloyd's Register Quality Assurance). Our former notified body "SNCH" did not renew their notification and consequently, we had to select a new one.

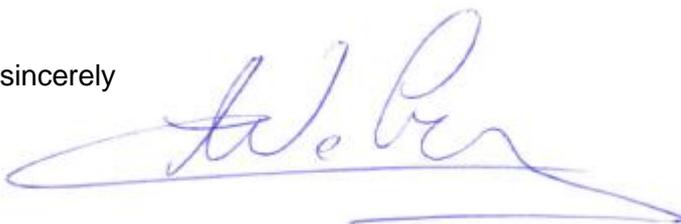
The transition process has been initiated already in April 2016. Due to the currently high workload of almost all notified bodies for medical devices, the project has taken more time than initially expected.

Please trust that it is our highest priority to finalise the transfer of our certificates as soon as possible.

The Belgian Health Authorities (FEDERAL AGENCY FOR MEDICINES AND HEALTH PRODUCTS - FAMHP) conducted an inspection at SMI AG in September 2017. All processes were found to be in compliance with applicable regulatory requirements. A letter was issued authorising SMI to continue to apply the CE mark with identification number 0499 on all certified Medical Devices until the reception of the new certificates. Please see annexed the relevant letter from the FAMHP

Please don't hesitate to contact us if you need further information.

Yours sincerely



Nico Weber
Quality Assurance & Regulatory Affairs Manager
SMI AG



DG post/Produits de santé/Dispositifs Médicaux

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SMI AG
Steinerberg 8,
4780 Saint Vith

Votre lettre du	Vos références	Nos références	Annexe(s)	Date
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Subject : Extension of the transition period regarding the use of the CE0499 marking for the EU Directive 93/42/CEE concerning medical devices and for the Royal Decree of 18 March 1999 related to medical devices.

Dear Sir, Dear Madam,

Following the analysis of the documents which you have brought to our attention about the search for a new notified body after the denotification of Société Nationale de Certification et d'Homologation, and following the inspection of the FAMHP carried out at your premises, we inform you that the FAMHP has decided to grant a prolongation of your transition period. This prolongation has no time boundary but can be interrupted immediately if the efforts made to obtain a new CE certification are considered insufficient or if some serious non conformity has been detected during an audit or an inspection.

During this prolongation period, the state of progress of the research for a new notified body, including the signature of contract, the determination of audit date, the realization of an audit or the delivery of a CE certificate, has to be brought to the attention of the FAMHP at all time. These elements have to be communicated by email (meddev@afmps.be). Please also take into consideration that during the transition period the FAMHP has the right to carry out announced or unannounced inspections at your premises. In a context of monitoring, the FAMHP can also witness the certification audit realized by your new notified body.

During this transition period and as a manufacturer, you can apply the identification number 0499 to your medical devices. However, please take into account that the FAMHP is not a notified body, and that we do not deal with placing on the market of new medical devices or with substantial changes in the meaning of the NBOG guidance NBOG_2014_03. As a result, the substantial changes of the technical files or of the quality manual have to be suspended and should be implemented only after the acquisition of a new CE certificate.

Please also note that FAMHP is granting a transition period only for certificates that were valid at the time of Société Nationale de Certification et d'Homologation denotification (15/10/2016). The transition period exclusively applies to medical devices manufactured according to the technical documentation that was in place at that time and which makes reference to the certificates in annex to this letter.

This prolongation is granted independently of further verifications about, amongst other things, the status, classification, and conformity with the dispositions presented in the Royal Decree of 18 March 1999 related to medical devices.

Please accept, dear sir, dear madam, the assurance of my highest consideration.

The General Administrator

Xavier De Cuyper

Certificate of Approval

This is to certify that the Management System of:

SMI AG

Steinerberg 8, St Vith, 4780, Belgium

has been approved by LRQA to the following standards:

EN ISO 13485:2012



David Derrick

Issued By: Lloyd's Register Quality Assurance Ltd

Current Issue Date: 20 December 2017

Expiry Date: 31 March 2019

Certificate Issue Number: 10049053

Original Approvals:

12 January 2018

Approval Certificate Number: LRQ 00001122/A

The scope of this approval is applicable to:

Design, development, manufacture and distribution of sterile and non-sterile medical devices for wound closure including sutures, skin-staples and staple removers and devices for haemostasis, surgical meshes, skin markers, biopsy devices and surgical blades.



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