SWISS MEDTECH

Welcome to MDR@noon

«The MRA is dead – Says the EU. Is it really?»

14 July 2021

Introduction

Welcome to Andreas Balsiger, Deepak Raju, Josefine Sommer, Maarten Meulenbelt and Nicolas Lockhart (Sidley Austin)

SIDLEY

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CONFIDENTIAL

MEMORANDUM – 2 JULY 2021

EU/EEA MARKET ACCESS FOR "SWISS LEGACY DEVICES"
POST ABANDONMENT OF SWISS-EU MRA

https://www.swiss-medtech.ch/en/news/mdr-portal

What happened on 26th May 2021 ?

- 12:00 AM: We know that Switzerland will become a third country by the end of today
- 2 PM: Industry agrees to offer for “small” amendment of MRA by EU commission → SECO
- 3:30 PM: Hand-outs for press conference by Federal Council to announce end of framework agreement
- 3:45 PM: EU-Commission sends out “Notice to Stakeholder”
- Midnight (without transition period):
  - CH manufacturers need EAR
  - Certificates from Swiss NB declared invalid
  - EAR need to be established in EU, not CH

From : DG SANTE B6 Medical Devices & DG TRADE — **31 March 2021**

The Commission services would like to inform that, to mitigate the risk of possible disruptions of supply of medical devices on the EU market, and to provide legal certainty to companies, the European Union will propose to Switzerland a limited modification to the current Mutual Recognition Agreement. An amendment is currently under preparation, aimed at granting certificates already issued in Switzerland for existing medical devices under the Swiss legislation equivalent to

...EU Medical Devices

Switzerland ends talks on EU partnership

The European Commission warned the decision will erode EU-Swiss relations.

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems, medical products and innovation
Medical devices, Health Technology Assessment

Brussels, 26 May 2021

NOTICE TO STAKEHOLDERS: STATUS OF THE EU-SWITZERLAND MUTUAL RECOGNITION AGREEMENT (MRA) FOR MEDICAL DEVICES

Reactions of EU member states

- **Spain**:
  Swiss products need EAR and EU-NB
  Importers need import licence from AEMPS
  Transition period until 30.09.2021

- **Italy**:
  Announcement that CH products with SQS certificate can no longer be imported

- **Germany**:
  Announcement in 4 federal states by ministries (Freiburg, Köln, München, Düsseldorf) that CH products with SQS certificate can no longer be imported

Legal opinion

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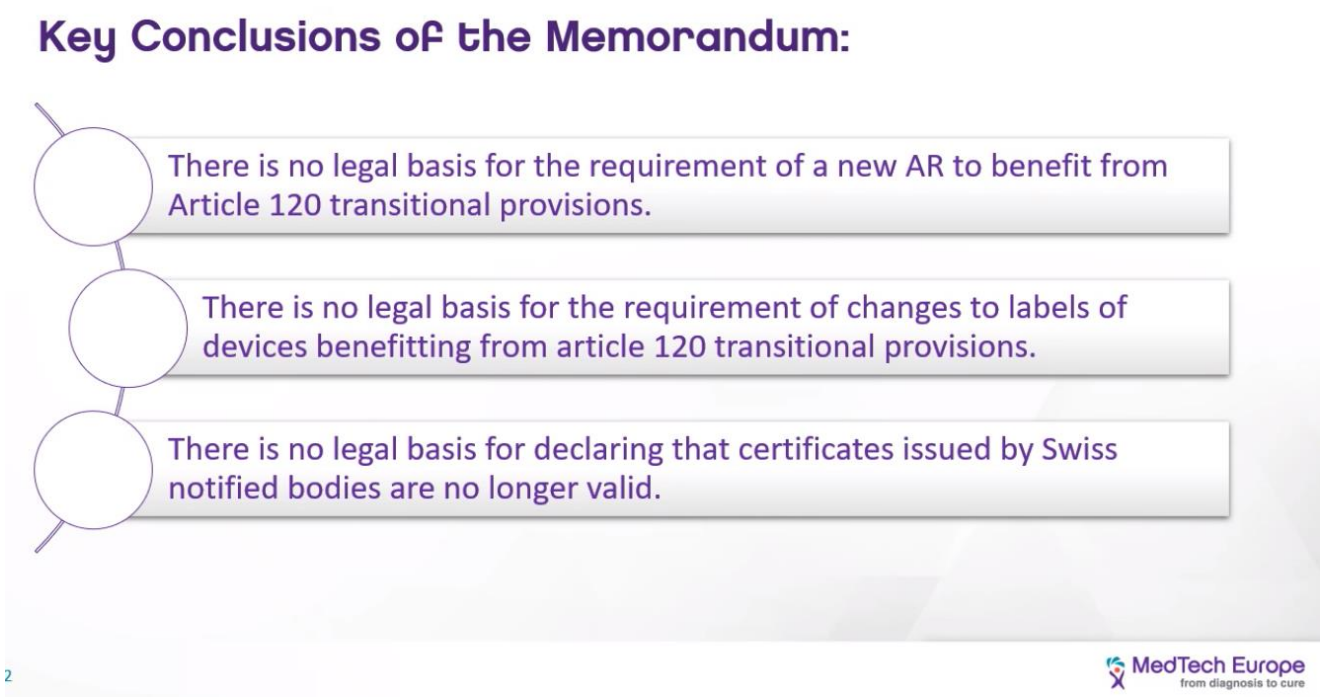

Outcome (oral communication by MTE on 12.07.2021):

- EU commission allows MDD products with Swiss AR acting as EAR – for now
- EU commission allows MDD products with Swiss NB certificate – for now