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Recommendation to all Swiss manufacturers of medical devices

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Currently, third-country requirements apply to Swiss manufacturers who place products on the European Union market in accordance with Regulation (EU) 2017/745[1] (Medical Device Regulation, MDR). Barrier-free access to the EU single market can only be achieved by updating the Mutual Recognition Agreement[2] (MRA). As such updating is not assured at present, Swiss Medtech recommends the following to all manufacturers of medical devices (according to MDR, Article 2, Number 30) with their registered offices in Switzerland:

- to include in their business considerations that they may have to comply with third-country requirements to place products on the EU market in accordance with the MDR. To do so, they would, in particular, have to
  - appoint an authorised representative with a domicile in the EU area (according to MDR, Article 11) who would take on the manufacturer's duties, including product liability, as a representative and
  - supplement the product labelling (labelling according to MDR, Article 2, Number 13) with the authorised representative and importer.

  NOTE: Depending on the complexity and scope of the product range, meeting these two requirements can take up to two years.

- to include in their business considerations various possibilities which could have an influence on updating the MRA and the transitional provisions of the MDR, in particular
  - the possibility that in the course of 2019 the Federal Council will, in principle, voice its support of the Institutional Agreement, which, according to the EU Commission, is the prerequisite for updating the MRA[3],
  - the possibility that Brexit is accompanied by a Europe-wide supply bottleneck and that exemptions will apply (according to MDR, Article 59),
  - the possibility that no sufficient MDR certification capacity by Notified Bodiescan be provided in time, which would also make it likely that exemptions will have to apply.

  NOTE: It is currently not foreseeable to what extent any supply bottlenecks could influence the transition periods of the current and future regulations.

Support: Guidance for appointing an authorised representative

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[1] Regulation (EU) 2017/745 dated 5th April 2017on Medical Devices, OJ L117 dated 5th May 2017, 1
[2] Agreement between the Swiss Confederation and the European Community on mutual recognition in relation to conformity assessments, SR 0.946.526.81, entered into force on 1st June 2002
[3] 17/12/2018: Press event by Johannes HAHN, Member of the EC in charge of European Neighbourhood Policy and Enlargement Negotiations, on EU-Switzerland relations – state of play