

The EU Medical Device Regulations and Switzerland

Transitional Regime for Swiss and Foreign Manufacturers of Medical Devices



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I. Introduction

The Swiss medtech sector is a key factor in the Swiss economy. It accounts for annual sales of 15.8 billion euros, which represents a GDP share of 2.3 percent.¹ Since approximately 70 percent of the business is generated through exports, market access to the members states of the EU as one of the main export markets is pivotal. Swiss manufacturers have enjoyed the benefits of a mutual recognition agreement (MRA) with the European Community, that entered into force on 1 June 2002, for almost two decades.² With the advent of the new EU medical device regulations³ replacing the pertinent directives⁴ in the near...

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