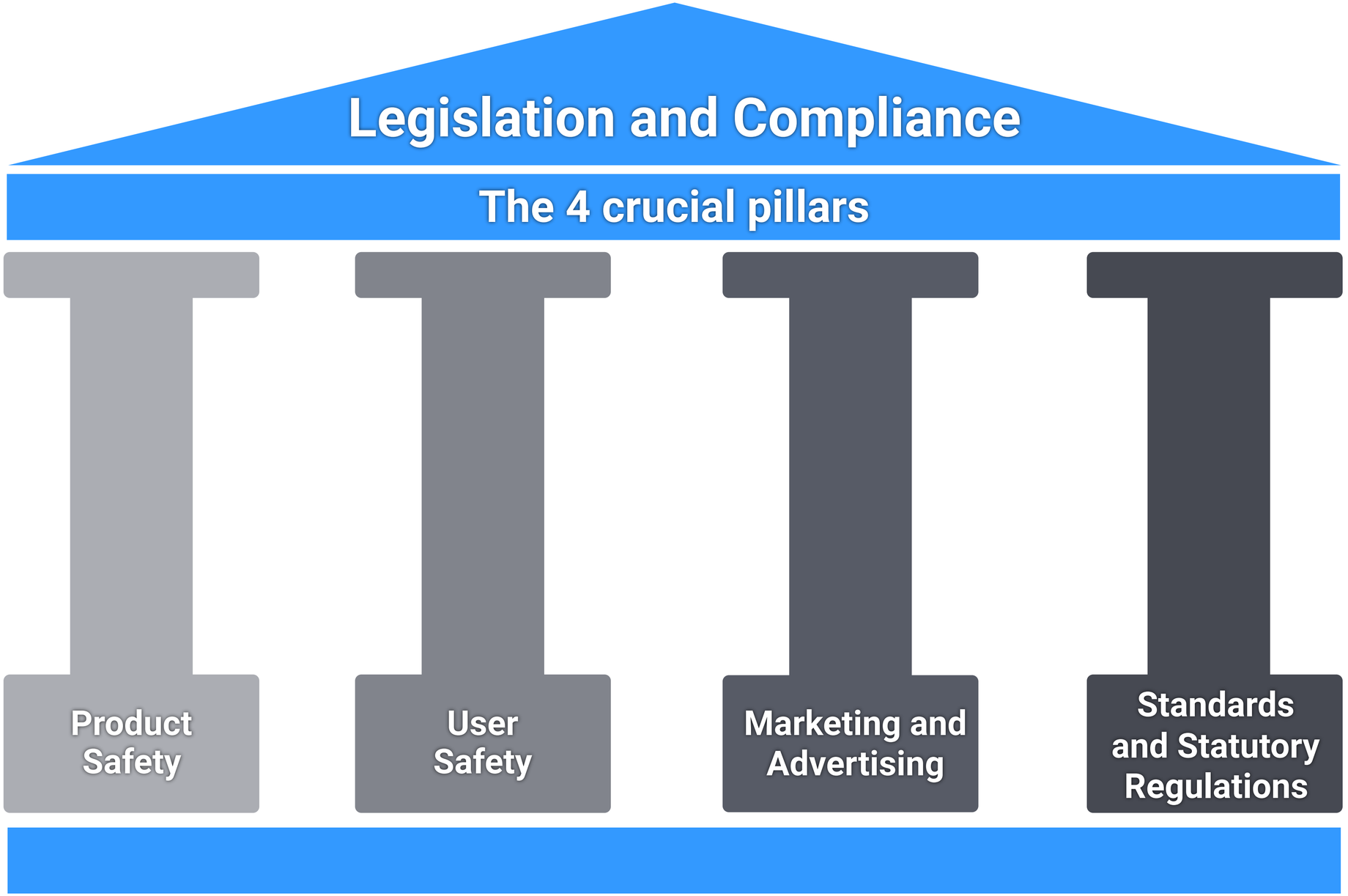
PEMF Prime Academy

Certified PEMF Expert

Module 10

PEMF - Legislation and Compliance

PEMF Prime Academy


Legislation and Compliance
The 4 crucial pillars
Product Safety
User Safety
Marketing and Advertising
Standards and Statutory Regulations

Legislation and Compliance

Product Safety

RULE Nr.1: A product has to be safe!

- Safe in terms of its design and functionality
- Safe in relation to its environment
- Safe under the influence of borderline situations

Legislation and Compliance

User Safety

RULE Nr. 2: A product should never be a threat to its user!

- The user may not be harmed physically
- Prevention of adverse effects associated with use of the product
- Eventual risk evaluation - more damage than good or vice versa

Legislation and Compliance

Marketing and Advertising

RULE Nr. 3: A product can only be marketed or advertised according to its "Intent of Use"!

- No health claims outside the intent of use
- No (false) promises at all
- Testimonials are ok, as long as the advertised claims do not lead to the average person being mislead to believe something about the product
- Any specific claims made other than those defined by the manufacturer, transfers the liability to the person/institution who originally made the claim
- Claims in connection with any specific diseases have to concur with the intent of use to its full extent
- All rules apply to all marketing and advertising, offline AND online - no exception

- **Despite the fact, that national rules and legislation my vary in detail, the above displayed prohibitions and restrictions apply world wide!**

Legislation and Compliance

Marketing and Advertising

Prohibited for Medical Devices:

- Healing promises
- Fake testimonials
- Paid testimonials with intentionally twisted facts
- Advertising using phrases, such as: “Research has shown…“ without citing the reference
- Using registered brand names or trade marks without permission

Legislation and Compliance

Marketing and Advertising

Examples on how the FDA assesses advertising and promotion of a medical device:

- The FDA`s legal authority for advertising and promotion is directed at the manufacturer, repacker, relabeler and/or a distributor
- Repackers, relabelers and distributors may or may not be under the control of the manufacturer
- Repackers and relabelers fall within the FDA`s definition of a manufacturer
- A distributor, who market a product with a new intent of use, will be deemed a repacker/relabeler and therefore a manufacturer

CAUTION!!!

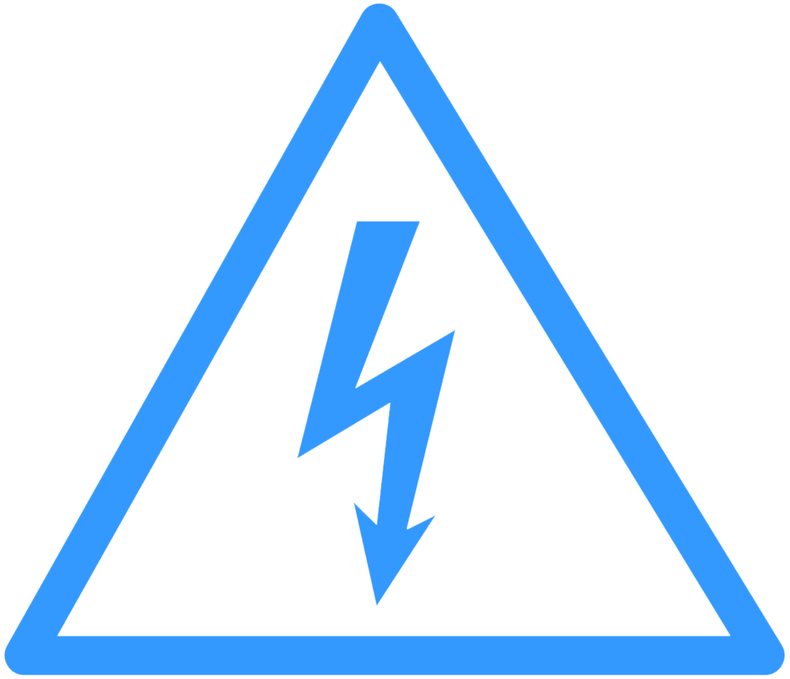
In simple words: If a distributor is advertising any other claims beyond the original "Intent of Use“ as defined by the manufacturer, the FDA will consider this distributor a manufacturer. In this case, the distributor becomes 100% liable to seek clearance for this/these claim(s), and has to deal with all related consequences!

Legislation and Compliance

Standards and Statutory Regulations

Product Safety

- Electrical Safety (refers to each electrically active item)
- USA: UL/FCC, CAD: CSA, Asia: CCC/eK/VCCI/..., Australia/New Zealand: AS/NZS, Europe: CE
- In order to ease global distribution, many norms and regulations have been "harmonized“ - meaning one certification for many countries
- Caution! Several countries still require a national certification



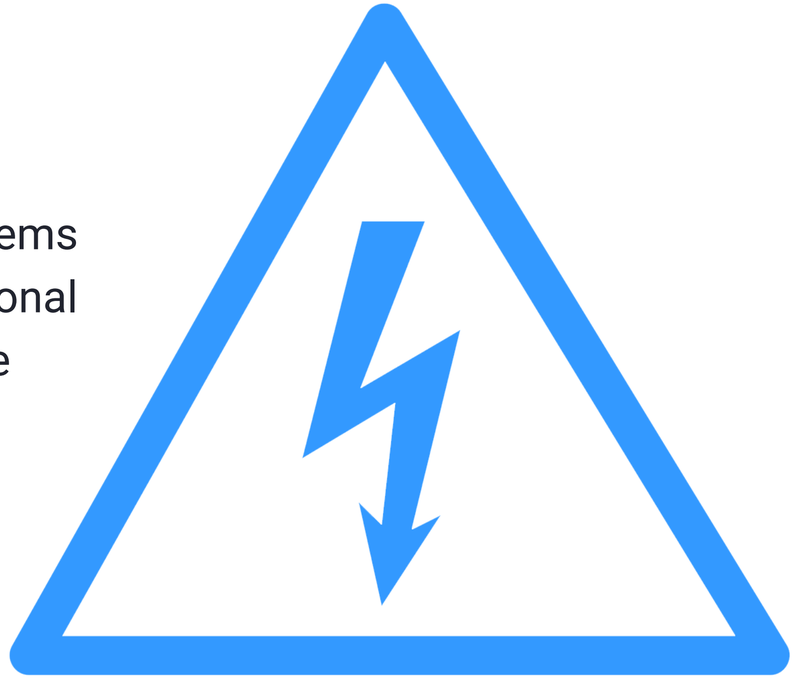
Legislation and Compliance

Standards and Statutory Regulations

Product Safety

Electromagnetic Compatibility (refers to the whole system)

Electromagnetic compatibility (EMC) is the ability of electrical equipment and systems to function correctly in their electromagnetic environment, by limiting the unintentional generation, propagation and reception of electromagnetic energy which may cause unwanted effects such as electromagnetic interference (EMI) or even physical damage in operational equipment.



Binding Standards for Medical Devices:

- EN 60601-1
- EN 60601-1-3
- CE/CB (incl. comprehensive third party lab testing)

Legislation and Compliance

Sample CB Certificate

IEC IECEE CB SCHEME

Ref. Certif. No.

IEC SYSTEM FOR MUTUAL RECOGNITION OF TEST CERTIFICATES FOR ELECTRICAL EQUIPMENT (IECEE) CB SCHEME

SYSTEME CEI D'ACCEPTATION MUTUELLE DE CERTIFICATS D'ESSAIS DES EQUIPEMENTS ELECTRIQUES (IECEE) METHODE OC

CB TEST CERTIFICATE CERTIFICAT D'ESSAI OC

Product
Produit

Name and address of the applicant
Nom et adresse du demandeur

Name and address of the manufacturer
Nom et adresse du fabricant

Name and address of the factory
Nom et adresse de l'usine

Note: *When more than one factory, please report on page 2*
Note: *Lorsque il y plus d'une usine, veuillez utiliser la 2ème page*

☐ Additional Information on page 2

Ratings and principal characteristics
Valeurs nominales et caractéristiques principales

Trademark (if any)
Marque de fabrique (si elle existe)

Type of Manufacturer's Testing Laboratories used
Type de programme du laboratoire d'essais constructeur

Model / Type Ref.
Ref. De type

Additional information (if necessary may also be reported on page 2)
Les informations complémentaires (si nécessaire,, peuvent être indiqués sur la 2ème page

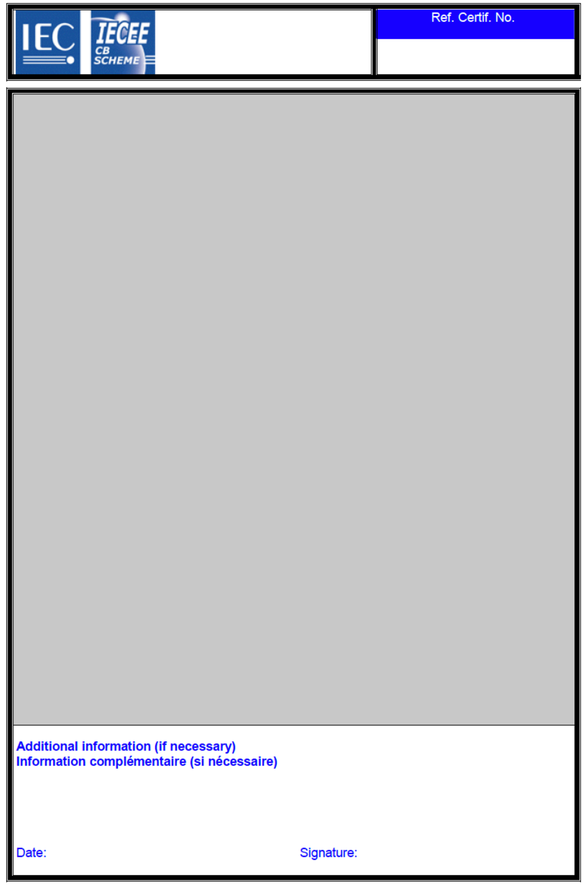
☐ Additional Information on page 2

A sample of the product was tested and found to be in conformity with
Un échantillon de ce produit a été essayé et a été considéré conforme à la

As shown in the Test Report Ref. No. which forms part of this Certificate
Comme indiqué dans le Rapport d'essais numéro de référence qui constitue partie de ce Certificat

This CB Test Certificate is issued by the National Certification Body
Ce Certificat d'essai OC est établi par l'Organisme **National de Certification**

Date: Signature:



IEC IECEE CB SCHEME

Ref. Certif. No.

Additional information (if necessary)
Information complémentaire (si nécessaire)

Date: Signature:

Legislation and Compliance

Standards and Statutory Regulations

Manufacturer Certification

ISO 13485:2016

Comprehensive Quality Management System for Medical Devices

Includes:

- Promotion and awareness of regulatory requirements as a management responsibility. Examples include 21 CFR 820, the Quality System Regulation for medical devices sold in the United States, enforced by the U.S. Food and Drug Administration (FDA), or the brand new Medical Devices Directive EU MDR 2017/745, replacing 93/42/EEC, required for doing legal business with medical devices in the European Union
- Controls in the work environment to ensure product safety
- Focus on risk management activities and design control activities during product development
- Specific requirements for the verification of the effectiveness of corrective and preventive actions

Legislation and Compliance

Sample 13485 Certificate

Certificate

mdc medical device certification GmbH
certifies that

Swiss Bionic Solutions Schweiz GmbH
Schulhausstrasse 17
8834 Schindellegi
Switzerland

for the scope

manufacturing and distribution of magnetic therapy devices

has introduced and applies a

Quality Management System

The mdc audit has proven that this quality management system
meets all requirements of the following standard

EN ISO 13485

Medical devices – Quality management systems –
Requirements for regulatory purposes

EN ISO 13485:2012 + AC:2012 - ISO 13485:2003 + Cor. 1:2009

Head of Certification Body

medical device certification mdc

DAkkS Deutsche Akkreditierungsstelle D-ZM-16002-05-00

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de

Legislation and Compliance

Standards and Statutory Regulations

Manufacturer Certification

MDSAP (Medical Device Single Audit Program)

The Medical Device Single Audit Program allows a MDSAP recognized Auditing Organization to conduct a single regulatory audit of a medical device manufacturer, that satisfies the relevant requirements of the regulatory authorities participating in the program.

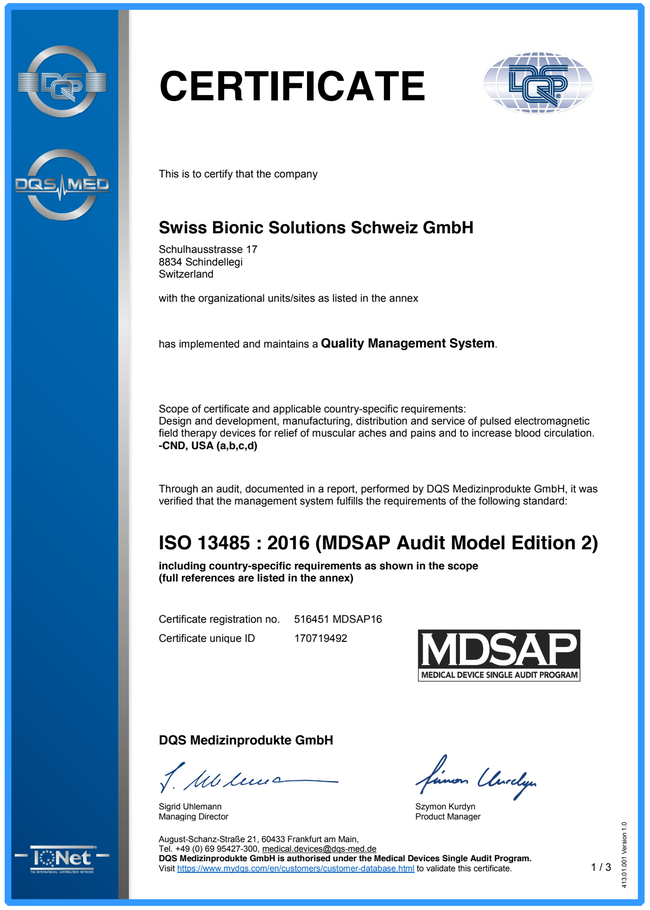
International partners that are participating in the MDSAP include:

MDSAP Members

- Therapeutic Goods Administration of Australia
- Brazil’s Agência Nacional de Vigilância Sanitária
- Health Canada
- Japan’s Ministry of Health, Labour and Welfare, and the Japanese Pharmaceuticals and Medical Devices Agency
- U.S. Food and Drug Administration

Legislation and Compliance

Sample MDSAP Certificate



CERTIFICATE

This is to certify that the company

Swiss Bionic Solutions Schweiz GmbH

Schulhausstrasse 17
8834 Schindellegi
Switzerland

with the organizational units/sites as listed in the annex

has implemented and maintains a **Quality Management System**.

Scope of certificate and applicable country-specific requirements:
Design and development, manufacturing, distribution and service of pulsed electromagnetic field therapy devices for relief of muscular aches and pains and to increase blood circulation.
-CND, USA (a,b,c,d)

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

ISO 13485 : 2016 (MDSAP Audit Model Edition 2)

including country-specific requirements as shown in the scope
(full references are listed in the annex)

Certificate registration no. 516451 MDSAP16
Certificate unique ID 170719492

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Szymon Kurdyn
Product Manager

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de
DQS Medizinprodukte GmbH is authorised under the Medical Devices Single Audit Program.
Visit https://www.mydqs.com/en/customers/customer-database.html to validate this certificate.

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413.01/001 Version 1.0