Legal principles for the qualification of products as medical devices

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Manual on borderline and classification for medical devices under Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices

Version 1 – September 2022

1.1.7. Borderline between medical devices and personal protective equipment

This section covers the borderline between products that may fall under the MDR or possibly under Regulation (EU) 2016/425 on personal protective equipment.

1.1.8.1 Rescue bag for patient transport

Background:

The rescue bag is designed for the transportation of patients during rescue operations. According to the manufacturer, the product is intended to protect the patient mechanically, as well as thermally, during the salvage. The mechanical protection of the head is ensured by additional padding in the head area. To stabilize the patient during the transport, as well as to attach safety equipment during different manoeuvres, side straps are sewed onto the rescue bag. Furthermore, the product aims to avoid repeated unpacking and packing of the patient during changes of the transportation device, e.g. from the emergency rescue sledge to the ambulance. The general intended purpose of the rescue bag is the patient´s support and protection.

Outcome:

The product in question enables stable and protected transport of patients in order to avoid the worsening of their state of health. The intended purpose of the product corresponds to the medical purpose of alleviation of, or compensation for, an injury or disability, according to Art. 2(1) of the MDR. It should be therefore qualified as a medical device. The risk class should be MDR class I, according to rule 1.

Please note that this entry refers solely to the qualification of the product as a medical device and that the manufacturer may also have to take into account other existing legislation for products used in emergency rescue.

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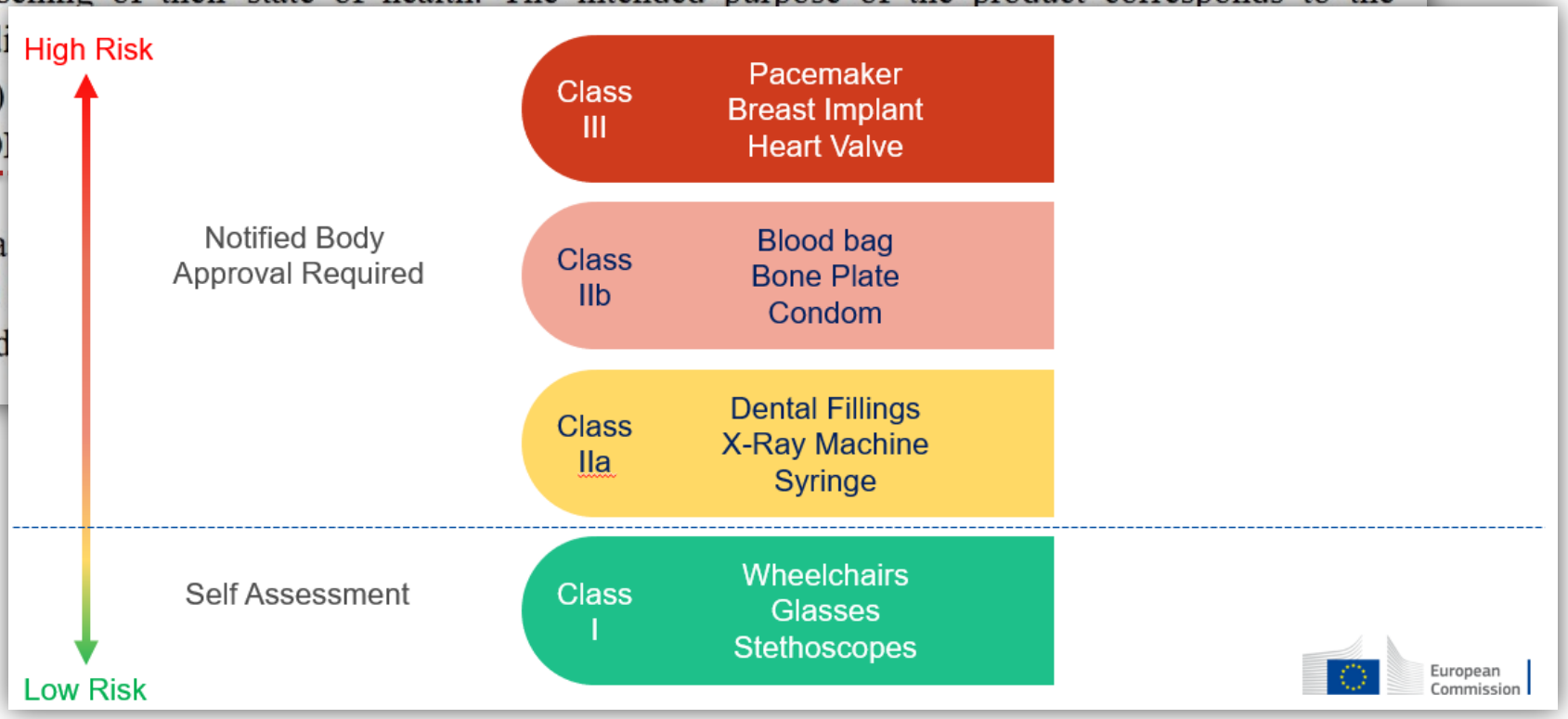

Which bags are concerned?

- Specifications

Is this a binding protocol?

- National Laws

What consequences does this have in Mountain Rescue?

- Users
- Manufacturers

Legal principle:

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 5 April 2017
on medical devices, amending Directive 2001/83/EC,
Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and
repealing Council Directives 90/385/EEC and 93/42/EEC

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Binding for all EU Member Countries?

National Agencies

Survey among ICAR Members & Mountain Rescue Organisations

Contact to EU Commission:
Medical Device Regulation Group

International Commission for Alpine Rescue

To the
Medical Device Coordination Group (MDCG)
Working Group on Borderline & Classification

Zurich, 28.11.2022

Regarding:
Discussion about certification of (air) rescue bags for patient transport as medical device

Dear Members of the Medical Device Coordination Group,

we address you on behalf of the International Commission for Alpine Rescue (ICAR).
It is with great interest that we read the following document:

> **Manual on borderline and classification for medical devices under Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices**
> Version 1 – September 2022

With reference to Section 1.1.7. and 1.1.8.1.

in which the Commission recommends the certification of rescue bags as a medical product:

> **1.1.7. Borderline between medical devices and personal protective equipment**
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>
> **1.1.8.1 Rescue bag for patient transport**
> **Background:**
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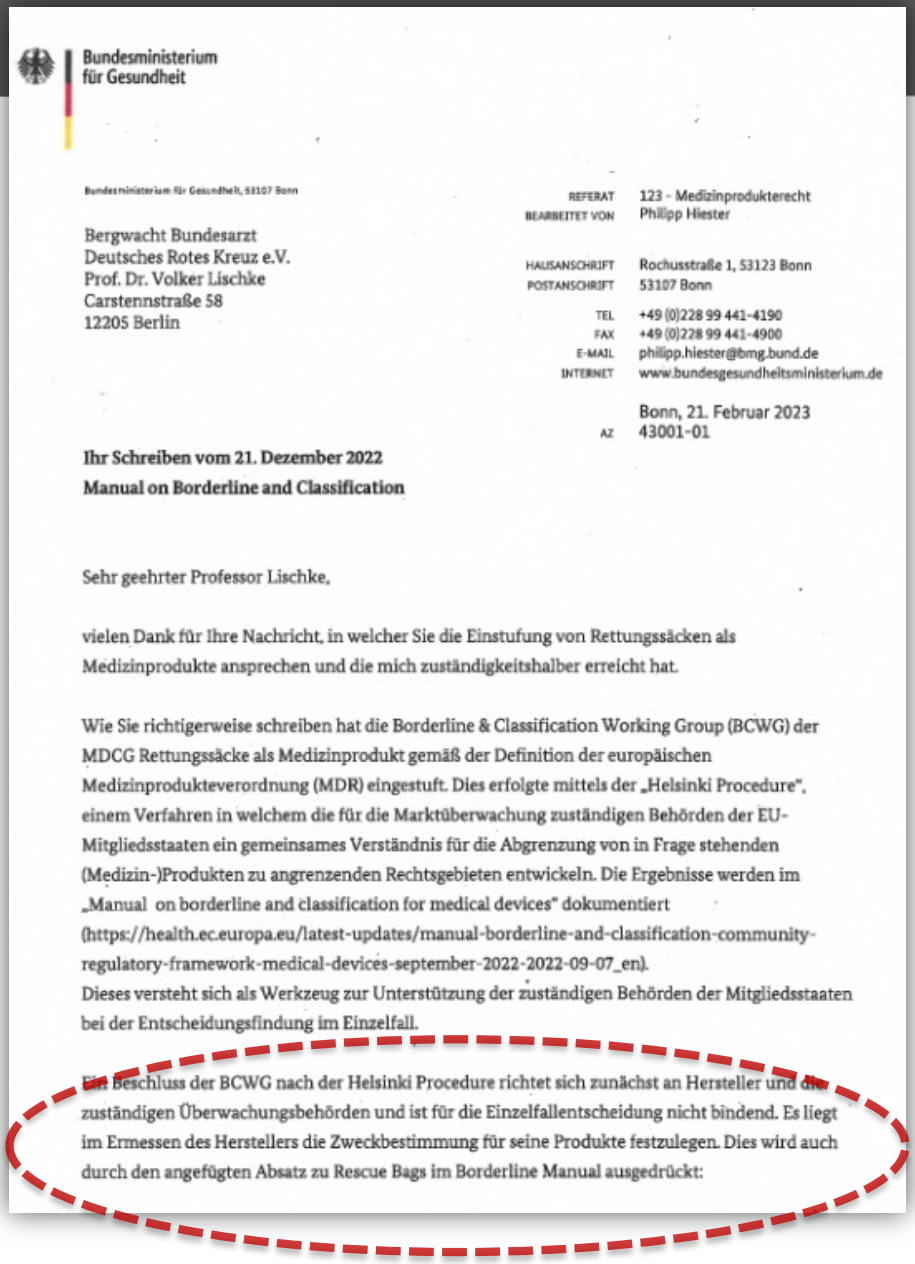

Bundesministerium
für Gesundheit

Bundesministerium für Gesundheit, 53107 Bonn

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Manual on Borderline and Classification

Sehr geehrter Professor Lischke,

vielen Dank für Ihre Nachricht, in welcher Sie die Einstufung von Rettungssäcken als Medizinprodukte ansprechen und die mich zuständigkeitshalber erreicht hat.

Wie Sie richtigerweise schreiben hat die Borderline & Classification Working Group (BCWG) der MDCG Rettungssäcke als Medizinprodukt gemäß der Definition der europäischen Medizinprodukteverordnung (MDR) eingestuft. Dies erfolgte mittels der „Helsinki Procedure", einem Verfahren in welchem die für die Marktüberwachung zuständigen Behörden der EU-Mitgliedsstaaten ein gemeinsames Verständnis für die Abgrenzung von in Frage stehenden (Medizin-)Produkten zu angrenzenden Rechtsgebieten entwickeln. Die Ergebnisse werden im „Manual on borderline and classification for medical devices" dokumentiert (https://health.ec.europa.eu/latest-updates/manual-borderline-and-classification-community-regulatory-framework-medical-devices-september-2022-2022-09-07_en).
Dieses versteht sich als Werkzeug zur Unterstützung der zuständigen Behörden der Mitgliedsstaaten bei der Entscheidungsfindung im Einzelfall.

Ein Beschluss der BCWG nach der Helsinki Procedure richtet sich zunächst an Hersteller und die zuständigen Überwachungsbehörden und ist für die Einzelfallentscheidung nicht bindend. Es liegt im Ermessen des Herstellers die Zweckbestimmung für seine Produkte festzulegen. Dies wird auch durch den angefügten Absatz zu Rescue Bags im Borderline Manual ausgedrückt:

Reply from the German Ministry of Health (21.02.2023)

„It is at the discretion of the manufacturer to determine the intended use of their products…..

…The BCWG decision does not result in any obligations for users to act…There is no obligation to only use products which are designated by the manufacturer as a medical device… It is therefore not required to exchange your products."

Contact @ Brussels at the European Commission:

Paul Piscoi, MD