PERMANENT REPRESENTATION
OF SWEDEN
TO THE EUROPEAN UNION

Brussels

Ambassador
Dag Hartelius

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Secretary-General
Ms Catherine Day
European Commission

Formal objection to a harmonised standard in the official journal of the European union

Dear Secretary-General,

Please find enclosed a formal objection to a harmonised standard published in the Official Journal of the European Union.

Yours faithfully,

Dag Hartelius

Copy to:
Mr Kohler, DG SANCO/B2
Ms Lecrenier, DG SANCO/B2
Mrs R. Weissenhorn, DG ENTR/13
Mrs E.Santiago, CENELEC

Postal address:
Square de Meeûs 30
1000 Brussels

Visitors' address:
Square de Meeûs 30
1000 Brussels

Telephone:
+32 2 289 56 11

Fax:
+32 2 289 56 00

E-mail:
dag.hartelius@foreign.ministry.se

Secretariat-General of the
European Commission

Copy to:
Mr. Kohler, DG SANCO/B2
Ms. Lecrenier, DG SANCO/B2
Mrs. R. Weissenhorn, DG ENTR/I3
Mrs. E. Santiago, CENELEC

NOTE TO DG SANCO, UNIT B2

FORMAL OBJECTION TO A HARMONISED STANDARD PUBLISHED IN THE OFFICIAL JOURNAL OF THE EUROPEAN UNION

STANDARD	EN ISO 13485:2003, Medical devices – Quality management systems – Requirements for regulatory purposes
DIRECTIVE:	Directive 90/385/EEC
	Directive 93/42/EEC
	Directive 98/79/EC

Sweden raises a formal objection against the medical devices standard EN ISO 13485:2003 in accordance with Article 6(1) of Directive 90/385/EEC, Article 5(3) of Directive 93/42/EEC and Article 5(2) of Directive 98/79/EC. The objection is raised because of non-compliance with the above mentioned medical devices directives, hereby referred to as the Directives.

We believe that an adequate management system standard would serve as an efficient tool to support and concretize the requirements in the Directives, thereby improving the implementation of the medical devices regulations. However, an insufficient or inadequate management system standard should not be harmonized and thereby possible to be used for claiming presumption of conformity with the medical devices regulations.

REASON FOR OBJECTION

1. We have doubts that this standard is covered by a valid mandate.

2. Despite section 3.3 of Annexes II, V and VI of Directive 93/42/EEC, Annexes 2 and 5 of Directive 90/385/EEC and Annexes IV and VII of Directive 98/79/EC the requirement of a quality system is not an essential requirement in the above mentioned Directives. We assume that only standards referring to essential requirements are to be harmonized, and accordingly, the standard should not have been harmonized at all.

   If the opposite assumption was to be true, other legal issues arise:

a) By its Annexes ZA, ZB and ZC, the standard pretends to cover essential requirements whereas we do not see any essential requirements as covered. It thus creates erroneously a presumption of conformity.
b) Furthermore, the standard does not indicate which provisions other than essential requirements are covered. Therefore, users might assume that all requirements of the Directives relating to quality management are covered by the standard. But this is not the case as will be demonstrated below.

3. The implementation of the quality system of EN ISO 13485:2003 does not assure compliance with the quality assurance requirements of the Directives. The requirements of the standard are not detailed enough to give the presumption of conformity with the Directives. In some cases, the standard is even less precise than the requirements in the Directives. Examples:

   a) Where the design, manufacture and/or final inspection and testing of the products, or elements thereof, is carried out by a third party the third indent of point (b) in section 3.2 of Annexes II and V of Directive 93/42/EEC and Annexes 2 and 5 of Directive 90/385/EEC requires a description of the methods of monitoring the efficient operation of the quality system and in particular the type and extent of control applied to the third party. The requirement in the standard (clause 4.1, and 8.5.1) is less precise than the requirement in the Directives. Where an organization chooses to outsource any process the standard only requires the organization to ensure the control over processes that affects product conformity with requirements. It does not require a description of the methods of monitoring.

   b) The first indent of point (c) in section 3.2 of Annex II of Directive 93/42/EEC and Annex IV of Directive 98/79/EC requires the manufacturer to have a description of any planned variants of the product. This is not a requirement of EN ISO 13485:2003. It should have been covered by clauses 7.2.1, 7.3.2 and 7.3.3 of the standard.

   c) The second indent of point (c) in section 3.2 of Annex II of Directive 93/42/EEC and the first indent of point (c) in section 3.2 of Annex 2 of Directive 90/385/EEC is only partly covered by the standard. The mentioned indents require the manufacturer to describe the standards that will be applied and the solutions adopted to fulfil the essential requirements which apply to the products if harmonized standards are not applied in full. The standard is less precise than the Directives. It only requires regulatory requirements to be specified (clause 7.2.1 c and clause 7.3.2 b of the standard).

   d) The seventh indent of point (c) in section 3.2 of Annex II of Directive 93/42/EEC requires a description of the solutions adopted as referred to in Annex 1, Chapter I, Section 2 of the Directives, eg. elimination or reduction of risks by safe design and construction, alarms and information to users. The requirement in the standard (clause 7.3.2 and 7.1) is less precise than the requirement in the Directive. It only requires the design and development outputs to meet the input requirements which shall include the output(s) of risk management.

   The above mentioned points are only examples of shortcomings of the standard in relation to the Directives. Therefore, we ask you to investigate this further.

A comparison of the requirements in Directive 93/42/EEC and EN ISO 13485:2003 is for examples a, b, c and d found in Annex 1 to this note.

In addition to the objections above we would like to stress that there are other shortcomings of EN ISO 13485:2003 and needs for improvements which should be taken into consideration. Examples of this are found in Annex 2 to this note.

DEVICES AFFECTED BY THIS OBJECTION

All medical devices where compliance with the essential requirements referred to in the above mentioned Directives has been presumed based on the compliance with EN ISO 13485:2003.

ANNEX 1

This annex compares the requirements in the standard against the requirements in the Directives described in the third point of the objection. Text from Directive 93/42/EEC is shown first (black text) and corresponding text from EN ISO 13485 is shown directly afterwards (blue text in italics).

Directive 93/42/EEC, Annex II, section 3.2.
Application of the quality system must ensure that the products conform to the provisions of this Directive which apply to them at every stage, from design to final inspection. All the elements, requirements and provisions adopted by the manufacturer for his quality system must be documented in a systematic and orderly manner in the form of written policies and procedures such as quality programmes, quality plans, quality manuals and quality records. It shall include in particular the corresponding documentation, data and records arising from the procedures referred to in point (c).

It shall include in particular an adequate description of:

OBJECTION 3.a

Directive 93/42/EEC, Annex II, section 3.2 b, third indent

(b) the organization of the business and in particular:

— where the design, manufacture and/or final inspection and testing of the products, or elements thereof, is carried out by a third party, the methods of monitoring the efficient operation of the quality system and in particular the type and extent of control applied to the third party;

EN ISO 13485:2003

4.1 General requirements

Where an organization chooses to outsource any process that affects product conformity with requirements, the organization shall ensure control over such processes. Control of such outsourced processes shall be identified within the quality management system (see 8.5.1).

NOTE Processes needed for the quality management system referred to above should include processes for management activities, provision of resources, product realization and measurement.

8.5.1 General

Records of all customer complaint investigations shall be maintained (see 4.2.4). If investigation determines that the activities outside the organization contributed to the customer complaint, relevant information shall be exchanged between the organizations involved (see 4.1).

OBJECTION 3.b

Directive 93/42/EEC, Annex II, section 3.2 c, first indent
(c) the procedures for monitoring and verifying the design of the products, including the corresponding documentation, and in particular:

— a general description of the product, including any variants planned, and its intended use(s),

EN ISO 13485:2003

7.3.2 Design and development inputs

Inputs relating to product requirements shall be determined and records maintained (see 4.2.4). These inputs shall include

a) functional, performance and safety requirements, according to the intended use,

b) applicable statutory and regulatory requirements,

c) where applicable, information derived from previous similar designs,

d) other requirements essential for design and development, and

e) output(s) of risk management (see 7.1).

7.3.3 Design and development outputs

The outputs of design and development shall be provided in a form that enables verification against the design and development input and shall be approved prior to release.

Design and development outputs shall

a) meet the input requirements for design and development,

b) provide appropriate information for purchasing, production and for service provision,

c) contain or reference product acceptance criteria, and

d) specify the characteristics of the product that are essential for its safe and proper use.

Records of the design and development outputs shall be maintained (see 4.2.4).

OBJECTION 3.c

Directive 93/42/EEC, Annex II, section 3.2 c, second indent
(c) the procedures for monitoring and verifying the design of the products, including the corresponding documentation, and in particular:

— the design specifications, including the standards which will be applied and the results of the risk analysis, and also a description of the solutions adopted to fulfil the essential requirements which apply to the products if the standards referred to in Article 5 are not applied in full,

EN ISO 13485:2003

7.3.2 Design and development inputs

Inputs relating to product requirements shall be determined and records maintained (see 4.2.4). These inputs shall include

a) functional, performance and safety requirements, according to the intended use,

b) applicable statutory and regulatory requirements,

c) where applicable, information derived from previous similar designs,

d) other requirements essential for design and development, and

e) output(s) of risk management (see 7.1).

7.3.3 Design and development outputs

The outputs of design and development shall be provided in a form that enables verification against the design and development input and shall be approved prior to release.

Design and development outputs shall

a) meet the input requirements for design and development,

b) provide appropriate information for purchasing, production and for service provision,

c) contain or reference product acceptance criteria, and

d) specify the characteristics of the product that are essential for its safe and proper use.

Records of the design and development outputs shall be maintained (see 4.2.4).

OBJECTION 3.d

Directive 93/42/EEC, Annex II, section 3.2 c, seventh indent
(c) the procedures for monitoring and verifying the design of the products, including the corresponding documentation, and in particular:

— the solutions adopted as referred to in Annex I, Chapter I, Section 2,

Directive 93/42/EEC, Annex I, Chapter I, Section 2
The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art.

In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order:

- eliminate or reduce risks as far as possible (inherently safe design and construction),
- where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated,
- inform users of the residual risks due to any shortcomings of the protection measures adopted.

EN ISO 13485:2003

7.3.2 Design and development inputs

Inputs relating to product requirements shall be determined and records maintained (see 4.2.4). These inputs shall include

a) functional, performance and safety requirements, according to the intended use,

b) applicable statutory and regulatory requirements,

c) where applicable, information derived from previous similar designs,

d) other requirements essential for design and development, and

e) output(s) of risk management (see 7.1).

7.1 Planning of product realization

The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1).

In planning product realization, the organization shall determine the following, as appropriate:
a) quality objectives and requirements for the product;
b) the need to establish processes, documents, and provide resources specific to the product;
c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance;
d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4).
The output of this planning shall be in a form suitable for the organization's method of operations.
The organization shall establish documented requirements for risk management throughout product realization. Records arising from risk management shall be maintained (see 4.2.4).

NOTE 1 A document specifying the processes of the quality management system (including the product realization processes) and the resources to be applied to a specific product, project or contract, can be referred to as a quality plan.

NOTE 2 The organization may also apply the requirements given in 7.3 to the development of product realization processes.

NOTE 3 See ISO 14971 for guidance related to risk management.

7.3.3 Design and development outputs

The outputs of design and development shall be provided in a form that enables verification against the design and development input and shall be approved prior to release.

Design and development outputs shall

a) meet the input requirements for design and development,

b) provide appropriate information for purchasing, production and for service provision,

c) contain or reference product acceptance criteria, and

d) specify the characteristics of the product that are essential for its safe and proper use.

Records of the design and development outputs shall be maintained (see 4.2.4).

ANNEX 2

EN ISO 13485:2003 – shortcomings and areas that are in need of improvements:

- There is no requirement or process described for post-market clinical follow-up in the standard. However, this is a requirement of Directive 93/42/EEC, Annex II, section 3.1 referring to Annex X.

- The product usability aspect should be part of the product development process in the standard as this is a requirement in the Directives.

- The definition of the organization in the standard does not support the regulatory need for definition of the legal manufacturer. There is a need to clearly address the tasks and responsibilities of the legal manufacturer to avoid discussions with regard to (internal) suppliers, distributors and weaknesses in respect to responsibilities in multinational companies/corporate groups. This is a common deviation observed in market surveillance performed by authorities following vigilance investigations.

- The requirements and processes for post market surveillance, complaint and vigilance handling, investigation methods, evaluation of investigation results and corrective and preventive action should be more detailed to focus on the special conditions for medical devices.

- The interaction between different processes of the medical device manufacturer (such as quality management process, risk management process, complaint handling, vigilance process, clinical evaluation and design) needs to be clarified in the standard. Market surveillance performed by authorities has shown that many of the described processes of the manufacturers are run in parallel without any, or with poor, interaction between them.

- A medical device specific standard for regulatory purposes should be more specific and concrete than the generic EN IS0 9001 and add more value for small and middle sized companies.

- At least the generally accepted key concepts of GHTF should be integrated in this standard.