International Standard

ISO 10993-4

Biological evaluation of medical devices —

Part 4: Selection of tests for interactions with blood

AMENDMENT 1

Évaluation biologique des dispositifs médicaux —

Partie 4: Choix des essais pour les interactions avec le sang

AMENDEMENT 1

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AMENDMENT 1

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Biological evaluation of medical devices —

Part 4:
Selection of tests for interactions with blood

AMENDMENT 1

3.4

Replace “ISO/TR 10993-20” with “ISO/TS 10993-20” in Note 1 to entry.

5.2.2

Replace the subclause heading with:

5.2.2 External communicating devices indirectly contacting blood

Delete the bullet points “cannulae”, “cell savers”, “intravascular catheters” and “blood collection devices”.

Replace “blood and blood product” with “saline and/or therapeutics” as follows:

— devices for the storage and administration of either saline or therapeutics, or both (e.g. tubing and bags);

Add the bullet point “blood monitors with indirect blood contact” as the second bullet point.

5.2.3

Add “blood collection devices” as a second bullet point, “cannulae” as a fourth bullet point, “cell savers” as a sixth bullet point and “devices for the storage and administration of blood and blood products (e.g. tubing and bags)” as an eighth bullet point.

Delete “or indirect” in the third bullet point as follows:

— blood monitoring devices with direct blood contact;

6.1.2

Add the following text to the second paragraph after the sentence “Only direct or indirect blood-contacting parts should be tested.”:

For direct contact haemocompatibility testing (e.g. direct haemolysis, complement activation, coagulation, platelet activation, haematology, in vitro or ex vivo thrombosis), testing should be conducted using only the direct blood contacting components of the device to minimize interference of non-direct blood contacting components on the results. For extract-based haemocompatibility testing (e.g. indirect haemolysis), testing should be conducted using only the direct and indirect blood-contacting components of the device. The test article shall be described and a justification shall be provided if the test article includes device components that include different tissue contact than described above.

Replace the fourth paragraph with:

As many tests for haemocompatibility are recognized to be generally surface-contact dependent (e.g. direct contact haemolysis, complement activation, coagulation, platelet activation, haematology, and in vitro or ex vivo thrombosis), such tests do not apply to indirect contact applications. For externally communicating medical devices or components that have indirect blood contact, only an indirect contact haemolysis test is generally recommended.

6.1.4

Replace NOTE 1 with:

NOTE 1 Changes in the manufacturing process (e.g. change in manufacturer), the use of different manufacturing aids that can affect the surface properties or the chemistry of the complete sterilized device can also impact haemocompatibility.

6.1.6

Replace Table 1 with: