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Third edition
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# Biological evaluation of medical devices —

## Part 7: Ethylene oxide sterilization residuals

*Évaluation biologique des dispositifs médicaux —*

*Partie 7: Résidus de stérilisation à l'oxyde d'éthylène*



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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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# Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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This document was prepared by Technical Committee ISO/TC 194, *Biological and clinical evaluation of medical devices,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 206, *Biological and clinical evaluation of medical devices,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).



This third edition cancels and replaces the second edition (ISO 10993-7:2008), which has been technically revised. It also incorporates the Amendment ISO 10993-7:2008/Amd 1:2019 and the Technical Corrigendum ISO 10993-7:2008/Cor 1:2009.

The main changes are as follows:

— allowable limits and extraction conditions have been derived based on the patient population and the duration of use;

— the use of a risk assessment to establish allowable limits has been permitted;

— additional guidance on product release has been provided;

— additional guidance on determining residuals and the factors that affect residual has been provided.

A list of all parts in the ISO 10993 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

# Introduction

As noted in the introduction to ISO 11135, when determining the suitability of ethylene oxide (EO) for sterilization of medical devices, it is important to ensure that the levels of residual EO and ethylene chlorohydrin (ECH) pose a minimal risk to the patient in intended product use. Therefore, it is important that the use of alternative materials and sterilization processes are considered during product design and development. EO is known to exhibit a number of biological effects. In the development of this document, consideration was given to these effects, which include irritation, organ damage, mutagenicity, carcinogenicity, and reproductive effects in humans and animals. Similar consideration was given to the harmful effects of ECH and ethylene glycol (EG). ECH can be formed when EO comes into contact with free chloride ions, whereas EG is a hydrolytic reaction product of EO and water. In practice, for most devices, exposure to EO and ECH is considerably lower than the maximum allowable limits established according to this document. No allowable limits are set for EG because risk assessment indicated that when EO residuals are controlled, it is unlikely that biologically significant residuals of EG would be present.

Requirements herein are in addition to the biological evaluation requirements as indicated in ISO 10993-1. The biological evaluation, combined with the EO-sterilization process residual limits, form the justification that an EO-sterilized device is safe for its anticipated contact duration. Maximum allowable residuals for ECH, when ECH has been found to be present in medical devices sterilized with EO, are also specified. Local effects (e.g. irritation) have been considered and are incorporated in the TCL as given in 4.3.6.2 and Annex D for EO, and in 4.3.6.3 and Annex E for ECH.

In this edition of this document (i.e. ISO 10993-7:2026), an uncertainty factor approach is used to derive EO and ECH exposure duration-specific tolerable intake (TI) values (expressed in µg/kg/d). Furthermore, this edition of this document (i.e. ISO 10993-7:2026) introduces the conversion of each EO and ECH TI value into subpopulation-specific cumulative exposure-allowable limit values (expressed in milligrams per device), which are used to determine the extent that EO and ECH, extracted under clinically relevant conditions and time-periods, needs to be reduced post-sterilization.

This edition of this document (i.e. ISO 10993-7:2026) applies a different approach as compared to ISO 10993-17:2023 to establishing allowable limits to make it useful for development, validation, and routine control of ethylene oxide sterilization in the manufacture of finished medical devices with focus on the risk assessments associated with three chemical constituents that are potentially left in medical devices sterilized with ethylene oxide. This document extends this knowledge further by calculating the largest amount of EO, ECH or EG that can be present in a medical device such that it would always meet the requirements of ISO 10993-17 when that device has been exposed to the validated sterilization cycle parameters. This maximum amount or allowable limit is expressed in milligrams per device deemed acceptable when taken into the body through exposure to that medical device. These allowable limits will help determine the appropriate sterilization parameters such as sterilant gas concentration and dwell, as well as aeration temperature and hold time when validating the sterilization process to be used for a product or group of products. Furthermore, the allowable limits can be used by regulatory bodies, manufacturers, and processors to optimize processes and aid in the selection and qualification of alternative materials in order to protect patient health.

# Biological evaluation of medical devices —

# Part 7:
# Ethylene oxide sterilization residuals

## 1 Scope

This document specifies allowable limits (AL) for residual ethylene oxide (EO) and ethylene chlorohydrin (ECH) in EO-sterilized medical devices, procedures for the measurement of EO and ECH, and methods for determining conformity so that devices can be released. Additional background, including guidance and a flowchart showing how this document is applied, are also included in Annexes A, B, C, D, E, F, G, H, I, J and K.

EO-sterilized devices or components that have neither direct nor indirect body or user contact (e.g. in vitro diagnostic devices) are out of scope of this document. This document does not apply to devices that have been demonstrated to not absorb or retain EO or its degradation product ECH, such as medical devices made exclusively of metal alloys and glass, see Clause C.5[228].

NOTE This document does not specify limits for ethylene glycol (EG). No device limits are specified for EG because the risk assessment in Annex F indicates that calculated allowable levels are higher than those likely to occur in a medical device.



## 2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 10993-1:2025, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 10993-23:2021, *Biological evaluation of medical devices — Part 23: Tests for irritation*

## 3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 10993-1 and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

**3.1**
**aeration**
part of the sterilization *cycle* (3.5) during which the sterilizing agent and/or its reaction products desorb from the health care product until predetermined levels are reached

Note 1 to entry: Aeration can be performed within the sterilization chamber or in a separate chamber or room.

[SOURCE: ISO 11139:2018, 3.7, modified — Note 1 to entry has been added.]

**3.2**
**allowable limit**
**AL**
amount of *residual* (3.19) ethylene oxide or ethylene chlorohydrin on a single device that is permitted as a condition of release for patient use

Note 1 to entry: Allowable limits are expressed in milligrams per device for each applicable exposure period. These limits represent acceptable biological risks for medical devices under the circumstances of their anticipated exposure duration.

**3.3**
**cumulative exposure**
total quantity of ethylene oxide and ethylene chlorohydrin that contacts the body for a specified period of time

Note 1 to entry: Cumulative exposure can apply when consecutive uses of the same device or of new devices of the same type for the same patient or user applies (e.g. when one device is used repeatedly over a specified period of time).

**3.4**
**concomitant exposure factor**
**CEF**
numerical *safety* (3.20) factor that accounts for patient exposure to the simultaneous use of other ethylene oxide sterilized medical devices different from the subject medical device

Note 1 to entry: CEF is calculated from the reciprocal of the number of devices (one divided by the number of devices) used during a procedure. The *default value* (3.6) of 0,2 assumes four other devices are used during a procedure, see 4.4.5 and Clause D.6 for further details.

**3.5**
**cycle**
set of sterilization process parameters



**3.6**
**default value**

value or factor used in the derivation of a *tolerable contact level* (3.22) or *tolerable intake* (3.24), in the absence of specific data [e.g. an *uncertainty factor* (3.26)]

[SOURCE: ISO 10993-17:2023, 3.5, modified — the "worst-case exposure dose" has been removed from the definition.]

**3.7**
**dose-response**
relationship of dosage to observable harm

Note 1 to entry: In general, there are two types of dose-response relationships. The first type is the change in response of an individual to a range of doses. The second type is the distribution of the response among individuals to a range of doses.

[SOURCE: ISO 10993-17:2023, 3.6]

**3.8**
**exhaustive extraction**
multi-step extraction conducted until the amount of material extracted in a subsequent extraction step is less than 10 % of that determined in the initial extraction step

Note 1 to entry: Based upon the boiling point of ethylene oxide (EO) (10,7 °C) and the knowledge that substances, other than EO and ethylene chlorohydrin, can be extracted from the device under evaluation, gravimetric analysis is not appropriate for determining the exhaustivity level.

[SOURCE: ISO 10993-18:2020, 3.15, modified — "by gravimetric analysis (or achieved by other means)" has been removed from the definition and Note 1 to entry has been added.]

**3.9**
**harm to health**
adverse reaction, such as altered morphology, physiology, growth, development, reproduction or lifespan that

a) impairs function of an organ or system, organism or (sub)population,

b) reduces capacity to tolerate an impaired function, or

c) increases susceptibility to other influences that impair function

Note 1 to entry: Examples of (sub)population include, but are not limited to: male, female, preterm neonates, adults.

[SOURCE: ISO 10993-17:2023, 3.8]

**3.10**
**load**
sterilization batch
sterilization load
product, equipment or materials to be processed together within an operating *cycle* (3.5)

[SOURCE: ISO 11139:2018, 3.155, modified — the admitted terms "sterilization batch" and "sterilization load" have been added.]

**3.11**
**implant**
medical device, or component thereof, that is intended to be introduced into the human body or to replace an epithelial surface or the surface of the eye, by means of surgical intervention and that is intended to remain in place after the procedure



Note 1 to entry: The duration of an implant remaining in the body is dependent on the clinical need.

[SOURCE: ISO 10993-1:2025, 3.21]



**3.12**
**irritation**
localized non-specific inflammatory response to single, repeated or continuous application of a substance/material

Note 1 to entry: Skin irritation is a reversible reaction and is mainly characterized by local erythema (redness) and swelling (oedema) of the skin.

[SOURCE: ISO 10993-23:2021, 3.7]

**3.13**
**lowest observed adverse effect level**
**LOAEL**
lowest concentration or amount of an identified constituent found by experiment or observation which causes detectable *harm to health* (3.9) to the target organism under defined conditions of exposure

[SOURCE: ISO 10993-17:2023, 3.13, modified — Note 1 to entry has been deleted.]

**3.14**
**minimally irritating level**
**MIL**
lowest amount per surface area of an identified constituent that is irritating to the tissue at the contact site as determined by valid experimental or observational evidence

Note 1 to entry: The minimally irritating level is expressed in microgram per centimetre squared ($\mu g/cm^2$).

[SOURCE: ISO 10993-17:2023, 3.15]

**3.15**
**modifying factor**
**MF**
mathematical product of *uncertainty factors* (3.26)

[SOURCE: ISO 10993-17:2023, 3.16]

**3.16**
**non-irritating level**
**NIL**
greatest amount per surface area of an identified constituent that does not elicit *irritation* (3.12) to the tissue at the contact site as determined by valid experimental or observational evidence

Note 1 to entry: The non-irritating level is usually expressed as milligram per centimetre squared per centimetre squared ($mg/cm^2$) or microgram per centimetre squared ($\mu g/cm^2$).

[SOURCE: ISO 10993-17:2023, 3.17, modified — 'usually' and 'milligram per centimetre squared per centimetre squared ($mg/cm^2$) or' have been added to Note 1 to entry. ]

**3.17**
**no observed adverse effect level**
**NOAEL**
greatest concentration or amount of an identified constituent found by experiment or observation which causes no detectable *harm to health* (3.9) to the target organism under defined conditions of exposure

Note 1 to entry: No observed adverse effect level is expressed in microgram per kilogram of body mass per day (µg/kg/d).

[SOURCE: ISO 10993-17:2023, 3.18]



**3.18**
**physiologically based pharmacokinetic modelling**
**PBPK modelling**
system of modelling biological effects taking into account metabolic and pharmacokinetic differences among species of animals

Note 1 to entry: Such data should be utilized whenever available and applicable to medical device anticipated exposure duration.

**3.19**
**residual**
quantity of ethylene oxide, ethylene chlorohydrin or ethylene glycol that remains in or on the product after ethylene oxide sterilization

**3.20**
**safety**
freedom from unacceptable risk

[SOURCE: ISO 14971:2019, 3.26]

**3.21**
**simulated-use extraction**
extraction using a method that simulates clinical use

Note 1 to entry: A simulated-use extraction is performed to estimate the type and amount of substances that are expected to be released from a medical device during its clinical use. A simulated-use extraction is designed to produce an extractables profile that represents the worst-case leachables profile, meaning that all leachables are also extractables and the levels of all individual extractables are at least equal to the level of all individual leachables.

[SOURCE: ISO 10993-18:2020, 3.35]

**3.22**
**tolerable contact level**
**TCL**
estimate of the surface-contact exposure to an identified constituent that is without appreciable *irritation* (3.12)

Note 1 to entry: Tolerable contact level is expressed in microgram per centimetre squared (μg/cm$^2$) of tissue at the contact site.

[SOURCE: ISO 10993-17:2023, 3.25]

**3.23**
**tolerable exposure**
**TE**
product of the *tolerable intake* (3.24), the body mass and the *concomitant exposure factor* (3.4)

Note 1 to entry: Tolerable exposure is normally expressed in milligrams per day to the patient.

**3.24**
**tolerable intake**
**TI**
estimate of the daily exposure of an identified constituent over a specified time period (e.g. acute, subacute, sub-chronic or chronic), on the basis of body mass, that is considered to be without appreciable *harm to health* (3.9)

Note 1 to entry: Tolerable intake is normally expressed in microgram per kilogram of body mass per day (μg/kg/d). It is derived to establish an *allowable limit* (3.2) for a medical device constituent.

[SOURCE: ISO 10993-17:2023, 3.26, modified — 'normally' has been added and 'toxicological exposure limit' has been replaced with 'an *allowable limit* (3.2)' in Note 1 to entry.]



**3.25**
**toxicological risk assessment**
determination of whether an exposure dose to a constituent can or cannot elicit appreciable *harm to health* (3.9)

[SOURCE: ISO 10993-17:2023, 3.29]

**3.26**
**uncertainty factor**
**UF**
numerical value that accounts for uncertainties when extrapolating a point of departure to individuals who can be exposed to a constituent of toxicological concern

EXAMPLE Extrapolation types include, but are not limited to: intraspecies, interspecies, dose route and study duration.

[SOURCE: ISO 10993-17:2023, 3.31]

## 4 Requirements

### 4.1 General

This clause specifies maximum ALs for residuals of ethylene oxide (EO) and ethylene chlorohydrin (ECH) for each individual medical device sterilized with EO. Local (acute) effects (e.g. irritation) have been considered and are incorporated in the TCL.

The requirements in this document shall be applied in addition to the requirements set out in ISO 10993-1. All applicable requirements of ISO 10993-1 shall take into account the EO residual level at the time of release for each individually designed medical device. The results of the biological assessment of the device may

lead to other limits than those specified in 4.3, which are designed to protect against local irritation and systemic effects.

Medical devices already on the market and tested to the previous edition of this document (i.e. ISO 10993-7:2008/Cor 1:2009 with ISO 10993-7:2008/Amd 1:2019) do not have to undergo the testing of this edition of this document (i.e. ISO 10993-7:2026). A review and confirmation that none of the issues identified in ISO 10993-1:2025, Clause 10 have occurred shall be carried out. If there are any changes, then a new biological risk assessment shall be carried out to demonstrate conformity to allowable limits. This may include re-testing to this edition of this document (i.e. ISO 10993-7:2026). The previous editions of this document reported a limit of 4 mg for EO and 9 mg for ECH for adults (70 kg body mass) with limited exposure [with the concomitant exposure factor (CEF) equal to 0,2 and an uncertainty factor 1 (UF1) of 10 for intra-species variability]. From a toxicological point of view, these values are not significantly different from the values calculated in this edition of this document (i.e. ISO 10993-7:2026) and thus, these changes in ALs do not warrant re-evaluating a product that met the limits of the previous edition of this document (i.e. ISO 10993-7:2008/Cor 1:2009 with ISO 10993-7:2008/Amd 1:2019).

A flowchart providing guidance for the application of this document to the determination of EO residuals in medical devices is given in Annex A.

NOTE 1 Information on the derivation of the limits in this document as well as other background information and guidance relevant to the use of this document is contained in Annexes C, D and E.

NOTE 2 Throughout this document, numbers calculated from formulae were rounded following the rules provided in NIST Special Publication 811[248]. Thereby, the number of (typically two) significant digits from the source literature were retained, and only increased (to typically three significant digits), where the calculated result was evaluated to provide the adequate amount of relevant information only with an increased number of digits. This evaluation is in line with NIST Special Publication 811:2008, B.7.2[248].



## 4.2 Categorization of devices



In establishing the maximum daily doses of EO and ECH that a medical device is allowed to deliver to patients, the medical device shall be categorized in accordance with the duration of body contact in accordance with ISO 10993-1:

a) limited exposure;

b) prolonged exposure;

c) long-term exposure.

If a device can be placed in more than one duration category, the more rigorous testing or evaluation considerations shall apply. If a device is intended for repeated or multiple usages, the decision into which duration category a device is placed shall take into account the potential cumulative effect, bearing in mind the period of time over which the cumulative exposure occurs. For example, a dialyzer cartridge is used for less than 24 h per treatment, but repeated usages of the same or a replacement cartridge for more than 30 d would categorize the cartridge as long-term exposure.

For medical devices that have very brief contact with the body, typically for less than one minute (e.g. lancets, hypodermic needles, capillary tubes), it can be possible to prepare a written justification that there is no potential for biological harm. For products with repeated use, the total exposure period shall be considered. However, for medical devices that can leave materials in contact with tissues after the medical device is removed (e.g. coatings, lubricants), a more detailed biological evaluation is required (see ISO 10993-1 for further guidance).

## 4.3 Allowable limits

### 4.3.1 General

For each medical device, the maximum exposure of EO and ECH to patients shall not exceed the AL using Formulae (1) and (2) based on the defaults in Table 1 for any of the applicable exposure categories (see 4.2). Alternative limits may be calculated based on risk assessment that accounts for device usage and patient

population. The procedure that was used to establish the tolerable intake (TI) is described in Annex D for EO and in Annex E for ECH.

Prolonged exposure devices carry additional limits for the first 24 h exposure period and, in the case of the long-term exposure devices, for the first 24 h period and the first 30 d period. These constraints set limits on the amount of EO and ECH that can be delivered to the patient during these early time periods.

The CEF uses a default value of 0,2 based on five devices used simultaneously. If data are available on the number of devices used at one time, for example, in multi-device systems, convenience kits, long-term exposure devices, then the default CEF of 0,2 may be modified (see 4.4.6, A.8 and D.6.1 for further justification).

The tolerable exposure (TE) shall be calculated based on the TI multiplied by body mass ($m_b$) and CEF.

$$TE = TI \times m_b \times CEF \quad (1)$$

where

$TE$ is the tolerable exposure in mg/d;

$TI$ is the tolerable intake in mg/kg/d;

$m_b$ is the body mass in kg;

$CEF$ is the concomitant exposure factor.

The AL shall be determined based on tolerable exposure multiplied by the days in the category unless an alternative limit can be justified. The lowest patient population mass, based on the anticipated exposure duration for the device, shall be used, see Clause C.4. The application of higher body masses associated for these sub population age groups, or lower body masses associated with younger sub population age groups, shall be justified and documented. See example in Clause K.11.

$$AL = TE \times \left( \frac{D}{N} \right) \quad (2)$$



where

$AL$ is the allowable limit in milligrams per device;

$D$ is the number of days of the medical device exposure duration in d;

$N$ is the number of devices used during this duration.

When the number of medical devices does not apply (e.g. the largest surface area of device which can be in contact with the body is not the same as the surface area of the device which is tested, or powder or liquid device), the “number of devices used during this duration” in Formula (2) shall be replaced by “the quantity of devices used during this duration”. The quantity should be expressed in $cm^2$, g or ml as appropriate considering the form of the device and the AL shall be expressed in $mg/cm^2$, mg/g or mg/ml respectively. The definition of AL shall be modified accordingly.

NOTE The number of devices ($N$) considered in Formula (2) is not related to the CEF, but number subject devices during the exposure duration used for a treatment or therapy, which can be 1 or more.

The intended population shall be documented.

**Table 1 — TE and AL default values for Formulae (1) and (2)**

| Exposure category | TI for EO<br>mg/kg/d | TI for ECH<br>mg/kg/d | CEF<br>default | Anticipated exposure duration, *D*<br>d |
|---|---|---|---|---|
| limited | 0,3 | 0,64 | 0,2 | ≤ 1 |
| prolonged | 0,3 | 0,27 | | ≤ 30 |
| long-term | 0,02 | 0,029 | | ≤ 25 000 d for adults (>16 y)<br>OR<br>≤ 5 840 d for paediatric (0 to 16 y)<br>AND<br>≤ 19 160 d for adult (> 16 y) |
| For medical devices used in a paediatric sub population age group, the factors to consider in the selection of fewer days (i.e. < 5 840 d) are described in Clause C.4 and D.6.8. | | | | |

### 4.3.2 Limited exposure devices

The AL for limited exposure devices are based on the TI value of 0,3 mg/kg/d for EO, 0,64 mg/kg/d for ECH, with *CEF* = 0,2 (default) as established in Clause D.4 and Clause E.5 respectively. The total EO and ECH cumulative exposure estimate obtained by simulated-use or exhaustive extraction shall be compared to the limited exposure AL, unless otherwise justified. Alternatively, an assessment targeted to evaluate toxicological risk associated with exposure to EO or ECH from the actual anticipated exposure duration of a specific device as well as more clinically relevant details for the device and indication can be used to determine appropriate allowable limits using Formulae (3) to (5).

$$AL = TI \times m_b \times CEF \times \left(\frac{D}{N}\right) \quad (3)$$

EXAMPLE

$$AL_{EO} = 0,3 \times m_b \times 0,2 \times \left(\frac{D}{N}\right) \quad (4)$$



where

0,3 is the limited exposure tolerable intake value in mg/kg/d;

$m_b$ is the body mass of anticipated patient population in kg;

0,2 is the default concomitant exposure factor;

*D* is the anticipated exposure duration up to 1 d;

*N* is the number of devices used during this duration.

$$AL_{ECH} = 0,64 \times m_b \times 0,2 \times \left(\frac{D}{N}\right) \quad (5)$$

where

0,64 is the limited exposure tolerable intake value in mg/kg/d;

$m_b$ is the body mass of anticipated patient population in kg;

0,2 is the default concomitant exposure factor;

*D* is the anticipated exposure duration up to 1 d;

*N* is the number of devices used during this duration.

Examples of AL calculations can be found in Annex K.

### 4.3.3 Prolonged exposure devices

The AL for prolonged exposure devices are based on TI value of 0,3 mg/kg/d for EO, 0,27 mg/kg/d for ECH, body mass $m_b$, and with CEF equal to 0,2 (default) as established in Clause D.4 and Clause E.5. The cumulative exposure estimate obtained by simulated use extraction or exhaustive extraction shall be compared to the applicable prolonged duration limit for up to 30 d, unless otherwise justified. Alternatively, an assessment targeted to evaluate toxicological risk associated with exposure to EO or ECH from the actual anticipated exposure duration of a specific device as well as more clinically relevant details for the device and indication can be used to determine appropriate allowable limits using Formulae (6) and (7).

$$AL_{EO} = 0,3 \times m_b \times 0,2 \times \left(\frac{D}{N}\right) \quad (6)$$

where

0,3 is the prolonged exposure tolerable intake value in mg/kg/d;

$m_b$ is the body mass of anticipated patient population in kg;

0,2 is the default concomitant exposure factor;

$D$ is the anticipated exposure duration up to 30 d;

$N$ is the number of devices used during this duration.

$$AL_{ECH} = 0,27 \times m_b \times 0,2 \times \left(\frac{D}{N}\right) \quad (7)$$



where

0,27 is the prolonged exposure tolerable intake value in mg/kg/d;

$m_b$ is the body mass of anticipated patient population in kg;

0,2 is the default concomitant exposure factor;

$D$ is the anticipated exposure duration up to 30 d;

$N$ is the number of devices used during this duration.

Prolonged exposure devices shall meet limited exposure AL in 4.3.2 during the first 24 h period. Examples of these calculations can be found in Annex K.

### 4.3.4 Long-term exposure devices

#### 4.3.4.1 Ethylene oxide

For EO, the tolerable exposure for long-term use devices is based on TI value of 0,02 mg/kg/d. The AL is determined by multiplying the TE with the number of days of anticipated exposure from a single or repeated use of a device for general populations (adults). Alternatively, an assessment targeted to evaluate toxicological risk associated with exposure to EO or ECH from the actual anticipated exposure duration of a specific device as well as more clinically relevant details for the device and indication can be used to determine appropriate allowable limits using Formulae (8) and (9).

$$TE_{\text{Adult EO}} = TI \times m_b \times CEF = 0,02 \times 60 \times 0,2 = 0,24 \text{ mg/d} \quad (8)$$