



DECLARATION OF CONFORMITY

For the classes of products: “Copper tubes for pipeline systems for medical gases and their mixtures, air, vacuum and anaesthetic gases scavenging systems”,

to the essential requirements described in Annex I of Directive 93/42/EEC and following additions given by the 2007/47/EC Directive (D.Lgs n.46 dated 24.02.97 and following additions given by the D. Lgs. Nr.37 dated 25.01.10).

The undersigned TONOLI S.r.l., with administrative office and plant in Via Don Primo Mazzolari, 44 - 25050 Passirano (BS) Italia - C.F. & VAT 03216680177, manufacturer of the medical device described in the technical file FT 01 “Copper tubes for pipeline systems for medical gas and medical gas mixtures, air, vacuum and for anaesthetic gases scavenging systems”, whose codes are reported in the attachment,

declares under its own responsibility that the device in question satisfies all the essential requirements of Annex I of the 93/42/EEC Directive and following additions given by the 2007/47/EC Directive.

For this purpose it hereby guarantees and declares under its own responsibility:

1. That the device in question satisfies the provisions applied by the Directive 93/42/EEC and the Directive 2007/47/EC, as prescribed in the Annex VII.
2. That the device in question is to be considered as belonging to **Class II A**, as stated in annex IX rule 2 of the above mentioned Directives.
3. That the device in question is commercialized in **NON STERILE** packaging.
4. That its committed to keep and available at disposal of the Notified Body and Competent Authority the product Technical File, specified on point 3 of the Annex VII of the above mentioned Directives, for a period of time of at least ten years from the last date of market input of the last production lot.
5. That the device comply with all the requirements of the following standards:
 - UNI EN ISO 15001:2012 “Anaesthetic and respiratory equipment - Compatibility with oxygen.”
 - UNI EN 13348:2016 “Copper and copper alloys - Seamless, round copper tubes for medical gases or vacuum”
 - UNI EN 1971-1:2019 “Copper and copper alloys - Eddy current test for measuring defects on seamless round copper and copper alloy tubes - Part 1: Test with an encircling test coil on the outer surface”
 - UNI EN 723:2009 “Copper and copper alloys - Combustion method for determination of the carbon content on the inner surface of copper tubes or fittings”
6. That the device in question is manufactured and placed on the market with first emission date 22/05/2020, as currently indicated in the present version of the product Technical File in the application scope of a conforming Quality System to the standard UNI EN ISO 9001 and UNI CEI EN ISO 13485 by KIWA CERMET ITALIA S.p.A., Notified Body number 0476 according to Directive 93/42/EEC and following additions given by the 2007/47/EC Directive, as prescribed in the Annex V of the above mentioned Directives (ref. Certificate n. MED 31611 with first issue date 22/05/2020, valid until 26/05/2024).

The current Declaration of Conformity has a maximum validity as the EC marking certificate released by the Notified Body reported in the attachment and is applied to all family product codes and to all fabrication lots manufactured after the first emission date. The Declaration of Conformity is confirmed at each lot release of conforming device as per the technical file in force.

The manufacturer further declares to have established and to maintain in order a suitable procedure for guaranteeing the post-marketing surveillance required by the Italian transpositions of the 93/42/EEC Directive and 2007/47/EC Directive.

Attachment 01: List of product codes

Attachment 02: EC marking Certificate

In witness

TONOLI S.r.l.
The legal representative
Massimo Castell

Date of issue of the declaration: 22/05/2020
Ed. /Is.: 01/0

Attachment: List of product codes

TONOLI'S Product code	Description
M1063	Copper tube Medicalfein R 6 x 1
M1083	Copper tube Medicalfein R 8 x 1
M1103	Copper tube Medicalfein R 10 x 1
M1104	Copper tube Medicalfein R 10 x 0,8
M1123	Copper tube Medicalfein R 12 x 1
M1124	Copper tube Medicalfein R 12 x 0,8
M1143	Copper tube Medicalfein R 14 x 1
M1153	Copper tube Medicalfein R 15 x 1
M1163	Copper tube Medicalfein R 16 x 1
M1183	Copper tube Medicalfein R 18 x 1
M1223	Copper tube Medicalfein R 22 x 1
M2083	Copper tube Medicalfein V 8 x 1
M2102	Copper tube Medicalfein V 10 x 0,6
M2104	Copper tube Medicalfein V 10 x 0,8
M2103	Copper tube Medicalfein V 10 x 1
M2122	Copper tube Medicalfein V 12 x 0,6
M2124	Copper tube Medicalfein V 12 x 0,8
M2123	Copper tube Medicalfein V 12 x 1
M2143	Copper tube Medicalfein V 14 x 1
M2144	Copper tube Medicalfein V 14 x 0,8
M2152	Copper tube Medicalfein V 15 x 0,7
M2153	Copper tube Medicalfein V 15 x 1
M2163	Copper tube Medicalfein V 16 x 1
M2164	Copper tube Medicalfein V 16 x 0,8
M2183	Copper tube Medicalfein V 18 x 1
M2222	Copper tube Medicalfein V 22 x 0,9
M2223	Copper tube Medicalfein V 22 x 1
M2282	Copper tube Medicalfein V 28 x 0,9
M2283	Copper tube Medicalfein V 28 x 1
M2284	Copper tube Medicalfein V 28 x 1,5
M2351	Copper tube Medicalfein V 35 x 1
M2352	Copper tube Medicalfein V 35 x 1,2
M2353	Copper tube Medicalfein V 35 x 1,5
M2421	Copper tube Medicalfein V 42 x 1

Attachment: List of product codes

TONOLI'S Product code	Description
M2422	Copper tube Medicalfein V 42 x 1,2
M2423	Copper tube Medicalfein V 42 x 1,5
M2541	Copper tube Medicalfein V 54 x 1
M2542	Copper tube Medicalfein V 54 x 1,2
M2543	Copper tube Medicalfein V 54 x 1,5
M2544	Copper tube Medicalfein V 54 x 2
M2644	Copper tube Medicalfein V 64 x 2
M2672	Copper tube Medicalfein V 66,7 x 1,2
M2673	Copper tube Medicalfein V 66,7 x 1,5
M2764	Copper tube Medicalfein V 76,1 x 1,5
M2765	Copper tube Medicalfein V 76,1 x 2
M2891	Copper tube Medicalfein V 88,9 x 2
M6081	Copper tube Medicalfein V 108,0 x 1,5
M6082	Copper tube Medicalfein V 108,0 x 2,0
M6083	Copper tube Medicalfein V 108,0 x 2,5
M5123	Copper tube Medicalfein V 12 x 1
M5152	Copper tube Medicalfein V 15 x 0,7
M5153	Copper tube Medicalfein V 15 x 1
M5222	Copper tube Medicalfein V 22 x 0,9
M5223	Copper tube Medicalfein V 22 x 1
M5282	Copper tube Medicalfein V 28 x 0,9
M5283	Copper tube Medicalfein V 28 x 1



Reg. Numero / Reg. Number	MED 31611	Revisione / Revision	0
Primo rilascio / First issue date	2020-05-22	Valido da / Valid from	2020-05-22
Scadenza / Valid until	2024-05-26	Ultima modifica / Last change date	2020-05-22

Pagina / Page 1 di / of 2

CERTIFICATE

Certificato CE del Sistema di Garanzia della Qualità EC Quality Assurance System Certificate

Si certifica che, sulla base dei risultati degli audit effettuati, il Sistema di garanzia di Qualità della Produzione dell'Organizzazione/ *We certify that, on the basis of the audits carried out, the Production Quality Assurance System of the Organization:*

TONOLI S.r.l.

Sede Legale e Operativa / Registered and Operational Headquarter:
Via Don Primo Mazzolari, 44
25050 Passirano, BS - Italia

è conforme ai requisiti applicabili della Direttiva 93/42/CEE e successive modifiche ed integrazioni, Allegato V, attuata in Italia con Dlgs. 46 del 1997/02/24 e successive modifiche ed integrazioni per le seguenti tipologie di Dispositivi Medici / *Is in compliance with the applicable requirements of 93/42/EEC Directive as amended, Annex V, transposed in Italy by Dlgs. 46 of 1997/02/24 as amended for the following Medical Devices:*

Tubi in rame per la realizzazione di impianti di distribuzione dei gas medicali e loro miscele, aria, vuoto e gas anestetici / *Copper tubes for pipeline systems for medical gases and their mixtures, air, vacuum and anesthetic gases scavenging systems*

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta
all'attività di direzione e coordinamento
di Kiwa Italia Holding S.r.l.
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Rif. rapporto di audit/ *Ref. audit report:* 20-21/11/2019Rif. analisi documentazione tecnica/ *Ref. technical documentation analysis:* 20/09/2019

Chief Operating Officer
Giampiero Belcredi

Firmato digitalmente da: BELCREDI GIAMPIERO
Data: 28/05/2020 09:19:05



Organismo Notificato n. 0476
Notified Body nr. 0476



Reg. Numero / Reg. Number	MED 31611	Revisione / Revision	0
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Pagina / Page 2 di / of 2

CERTIFICATE

Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Tubi in rame per la realizzazione di impianti di distribuzione dei gas medicali e loro miscele, aria, vuoto e gas anestetici / Copper tubes for pipeline systems for medical gases and their mixtures, air, vacuum and anesthetic gases scavenging systems

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 1112

Modello / Model:

Tubo di rame Medicalfein / Medicalfein copper tube

Codici / Codes:

MXXXX

La lista completa dei codici, relativi ai modelli certificati, è disponibile presso Kiwa Cermet Italia./ The complete list of the codes related to the certificated models is available at Kiwa Cermet Italia. Il presente Certificato è soggetto al rispetto dei requisiti contrattuali di Kiwa Cermet Italia ed è valido solo per le tipologie di dispositivi sopra identificate soggette a sorveglianza/ This Certificate is subject to Kiwa Cermet Italia regulations and it is valid only for the above mentioned Medical Devices that are subject to survey. L'allegato tecnico è parte integrante del presente Certificato./ The technical sheet is an integrating part of this Certificate.

Kiwa Cermet Italia S.p.A.
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CERMET

Chief Operating Officer
Giampiero Belcredi

Firmato digitalmente da:BELCREDI GIAMPIERO
Data:28/05/2020 09:19:27

CE

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