Meca-inoX
SINCE 1955

Compliance with Regulation (EC) No. 1935/2004 for the parts of equipment to come into contact with foodstuffs.

At the right,

Framework Regulation (EC) No. 1935/2004

The Regulation (EC) No. 1935/2004 (or 'framework regulation') of October 27th, 2004 sets the General requirements that apply to materials and articles intended to come into contact directly or indirectly with food, food products and food drinks placed on the Community market in order to ensure a high level of consumer protection. **It applies to materials and articles intended to be placed in contact with foodstuffs or which can be reasonably predicted to come into contact with food or that they will transfer their constituents to food.**

Foodstuffs, mean food as defined in article 2 of Regulation (EC) n ° 178/2002 namely drinks, chewing gum and any substance, including water, intentionally incorporated into food during their production, preparation or treatment. Such substance as feed, drugs or tobacco for example are therefore not within the scope of this regulation.

The Meca-Inox valves, intended for the food industry in broad sense, are subject to the Regulation (EC) No. 1935/2004 in respect of materials and equipment used in the production, processing, storage or transport of foodstuffs if they have vocation to carry food or fluids *coming* into contact directly or indirectly with food. In the case of fluids without any contact with food, this regulation does not apply.

According to Regulation (EC) No. 1935/2004, the materials and the parts of Meca-Inox valves intended to come into contact with foodstuffs, are therefore made in accordance with the **good manufacturing practices (CE) No. 2023/2006. Under normal or predictable *conditions of use* (see table 1)**, it has been **verified that they don't yield to foodstuffs of the components in a higher quantity than 10 mg/square decimeter on the basis of standardized test methods**.

Concerning Meca-Inox valves, this Regulation (EC) No. 1935/2004 at the European community level, applies to all plastic parts in the fluid stream, namely: Body seals, ball seats and stem thrust seal and if necessary at the cavity fillers, guide rings and cavity fillers seats.

For these plastic parts, **full traceability of the chain of production**, from raw material to integration in valves production batches, has been implemented. After verification of the conformity of used plastics compositions, overall migration tests made **on reference batches of our series parts, standard simulants A, B, D2 according to the thermal cycle MG5 or MG7 repeated 3 times to ensure their inertia of contaminant release in foodstuff**. These tests were conducted in partnership with **accredited laboratories**, guaranteeing the conformity of our plastic parts to Regulation **(EU) No. 10/2011** (which repeals directives no. 2002/72/EC, no. 80/766/EEC and 81/432/EEC) for **multi contact applications**.

Table 1 summarizes the Meca-Inox product lines for which this approach was fully deployed and therefore for which a **certificate of compliance of plastic materials in contact with the fluid to the Regulation (EC) No. 1935/2004** may be issued at any time at the request of our customers via **the order of an article "9CERTIF-CE1935".**

According **to regulations on labelling and traceability**, starting September 2016, all these product lines will be delivered with a **stainless steel tag** which will state this compliance by the mention **'CE1935-Plastics'** and will remind the **equipment production batch number.**

Applications	Standard			Special		
Types	PN4I (Valve)	CL4 (Check valve)	VC4 (Viewer)	PS4I – PG	PZ4I	PH4I
Limites d'utilisations Alimentaires des pièces plastiques suivant (CE) 1935/2004	All foodstuff, ingredients & fluids for food & drink process **-20°C to +121°C**, all contact times			CO_2 and other food & drink process gas **-50°C à +121°C**, all contact time	**Same as PN4** + steam, hot water and oils for food & drink process **+20°C to +250°C**, all contact time	All foodstuff, ingredients & fluids for food & drink process **-50°C to +50°C**, all contact time

Table 1: Meca-Inox range of products in accordance with Regulation (EC) No. 1935/2004 off specific national provisions

This certificate **may** also be issued for other families of Meca-Inox valves, upon request before order only (e.g. valves **PY4 and PY4CY for cryogenic liquid** food such as Nitrogen in the temperature range - 200 °C to + 121 ° C. Please contact our Sales Department for more information.

Siège Social & Services Commerciaux:
1, rue de la Croix des Maheux
F-95000 CERGY
Tel. +33 (0)1 78 47 80 00
Fax.+33 (0)1 78 47 80 01

Email : infos@meca-inox.com

Web : www.meca-inox.com

Site Industriel:
12, rue de la Haute Borne
F-27140 GISORS
Tel. +33 (0)1 78 47 80 10

Specific national provisions: Case of stainless steels:

In the absence of specific measures of the European Union, the regulation framework (EC) No. 1935/2004 indicates that for stainless steels, specific national provisions exist. As such, **on the 13th of January 1976 France published** a specific decree on the **stainless steels for food applications**, which states the following chemical composition:

- **Chromium content (Cr) above 13%,**
- **Tantalum (Ta), Niobium (Nb), Zirconium (Zr) contents less than 1%,**
- **Contents of Molybdenum (Mo), Titanium (Ti), Aluminium (Al) and Copper (Cu) less than 4%**

In respect of food applications, MECA-Inox proposes valves with the metal parts in contact with the fluid made of stainless steel 316 L type 1.4409 and 1.4404. These materials standards do specify all of these chemical elements and therefore, to ensure compliance with the French specific regulations on stainless steels, we perform chemical analyses on samples from the batches used for the manufacture of bodies, ends, stems and balls. Except contrary requisition of our professional customers, these chemical composition tests are committed to all our valves for the French market.

The commitment of these specific chemical analysis on stainless steel parts involves additional costs and the implementation of specific traceability which cannot be requested before production and caused a change in the code reference of the product.

To clearly **identify the equipment produced following this dual compliance with regulations (EC) No. 1935/2004 and the French decree of January 13, 1976,** each produced equipment has **a specific unique production traceability number as well as a stainless steel tag number containing the logo standard with the "glass and fork '** as described in the Regulation (EC) No. 1935/2004.

Legal Responsibilities:

With regard to **professional use** of materials and articles intended to come in contact with food, paragraph 1 of article 17 of Regulation (EC) n ° 178/2002 **requires the food business operator** to verify that facilities complies with the rules that apply to them. Article 1 of the Regulation (EC) No. 852/2004 reminds that "**primary responsibility for food safety is the responsibility of the food business operator**».

Specific local regulations, similar but different from the ones of January 13, 1976 in France on stainless steels may exist in the 27 countries of the European Community. It is therefore the responsibility of operators in the food sector, users of our equipment, to order us according to these regulations.

In case of doubt for the food business operator, Meca-Inox recommends the application of dual compliance to the Regulation (EC) No. 1935/2004 and the Decree of 13 January 1976 on stainless steels. Thus, in respect with the principle of community mutual recognition, valves are necessarily compliant with potential local regulation on stainless steels for any European country market, even if it is slightly different from the French regulations.

This note cancels and replaces all previous Meca-Inox communication notes on this regulation.

The certificates issued by Meca-Inox in respect of the conformity of our valves and equipment to Regulation (EC) No. 1935/2004 before January 1, 2016 were compliant with the regulations in force on their date of issue. The transition period for full implementation of the Regulation (EU) No. 10/2011 relating to the trials of global migration under representative conditions on finished ended since December 31, 2015. So, old issued certificates cannot be used to justify conformity of our equipment since that date. Therefore, please contact our sales department to discuss the terms of programming new certificates for your equipment delivered since that date.

Gisors, the 1st of September 2016,

Lionel FERRAND
Quality Director