



MACCHINE PER LAVAGGIO  
INDUSTRIALE DI INTERNI

HEADS FOR INDUSTRIAL  
WASHING OF CONTAINER

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## FDA Conformity Declaration

**For consumers goods intended to come into direct or indirect contact  
with foodstuff and for application in pharma plant engineering**

Customer:

Customer code:

Order N°:

Hereby we: **Officina Meccanica Bolondi Ivano**  
**Via A.Volta, 4 42027 Montecchio Emilia (RE)**  
**Italy**

The Products: **XM 15/30/60/200**  
**XC 61**  
**XT 76**  
**RW 190**  
**RW 030**  
**RT 225/235/255/111**

Is intended to come into contact with foodstuff

The product complies with the current version of the following regulations or regulatory codes:

FDA 21 CFR 1777.1550

FDA 21 CFR 1777.2415

USP Class VI Title 87 (50° C)

USP Class VI Title 88 (121°C)

### **Materials used:**

The materials used for the manufacture of the product comply with the current version of the positive list of FDA regulatory codes above listed

If used correctly, the following materials come into contact with foodstuffs:

- PTFE
- PEEK
- Aisi 316L

### **Extraction test**

#### **Foodstuff simulant**

50% sodium Ethanol  
n-Heptane

#### **Migration conditions**

2 hours /reflux temperature  
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The maximum limiting value of extractable substance defined in the regulatory codes above listed are complied with under the following test conditions and were proven in a corresponding test.

### **USP Class VI Tests**

The tests according to USP Class VI Title 87 (50°C) and Title 88 (121° C) were carried out and passed.

### **BSE/TSE**

The above-mentioned product is certified to comply with EMA/410/01 revision 3.

### **Application**

The above-mentioned product is suitable for any type of food contact.

Any restrictions derived from the information contained in the technical documentation relating to the maximum storage time and the temperature limits shall also apply.

20/03/2019 Montecchio E. RE

**Bolondi Ivano**

Chief Executive Officer

