

## Declaration of conformity to legal standards

Galvano Wullimann AG (Wullimann) sees itself as a surface finisher of objects and products on a contract basis. According to the REACH guidelines, the coating of products constitutes "light processing"<sup>1</sup> of a product. The following declarations refer explicitly to the surface treatments applied by Wullimann. Wullimann does not manufacture products or articles. The base materials to be finished are not taken into account in the consideration and evaluation. The responsibility regarding any conformity or restrictions on the materials used for the articles and (complex) objects (substances and mixtures are irrelevant here, as the shape, surface or design of the object is relevant for the function) lies explicitly with the client (customer) as described in the REACH Regulation guidelines.

Wullimann checks at regular intervals whether new substances are regulated in the following legal standards and updates the declaration of conformity on an ongoing basis.

With reference to the following legal standards, the following surface treatments are considered by Wullimann:

- Electroplated nickel
- Chromium from chromium(III) electrolytes
- Achrolyte
- Electroless nickel
- Anodized with various color inclusions
- Electropolishing
- Zinc phosphate with various post-treatments
- Zinc with various conversion layers
- Zinc/nickel alloy with various conversion layers

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<sup>1</sup> [https://echa.europa.eu/documents/10162/2324906/articles\\_de.pdf](https://echa.europa.eu/documents/10162/2324906/articles_de.pdf)

## Regulation (EC) No. 1907/2006 (REACH, EU Chemicals Regulation)

Substances and substances in preparations, in electrolytes and in solutions are used specifically as downstream users for the processing of surfaces. Our process suppliers were and are responsible for the proper registration of the substances.

Communication in the supply chain according to Art. 33 REACH Regulation

Communication in the supply chain is particularly necessary if the limit value of 0.1% by weight (w/w) of a substance of very high concern (SVHC) is exceeded in an article.

We regularly check the ECHA (European Chemicals Agency) candidate list in order to fulfill our duty to inform our customers.

The final layers applied by us in our finishing processes generally do not contain any SVHC substances or fall below any applicable limit values.

The corrosion resistance of surface coatings with zinc and zinc alloys is usually post-treated with a conversion coating. These very thin layers may contain small amounts of cobalt and cobalt compounds, the starting materials of which are listed in the candidate list in the treatment electrolytes. In relation to the coated product, the limit value of 0.1 weight % is generally not exceeded, provided the base material composition does not contain cobalt.

Annex XIV REACH Regulation

The substances listed in Annex XIV of the REACH Regulation require a time-limited authorization for use. The coatings we apply do not contain any substances listed in the list of substances subject to authorization. If substances used by us are included in Annex XIV, the further procedure (substitution or application for authorization) can be agreed with the customer.

Annex XVII REACH Regulation

The substances listed in Annex XVII of the REACH Regulation contain all the restrictions imposed under the REACH Regulation and the former Directive 76/769/EEC. Each entry shows a substance or a group of substances or a substance in a mixture and the associated restriction conditions.

Nickel and nickel alloy coatings should not be applied to products that are in permanent contact with human skin or are used in the human body<sup>2</sup>.

## Directive (EU) 2011/65 and (EU) 2015/863 (Restriction of Hazardous Substances, RoHS)

The aim of this directive is to ban problematic components from electronic waste. In accordance with Annex II of Directive (EU) 2011/65, the percentages represent the maximum permissible concentrations in homogeneous materials in percent by weight.

1. Lead (Pb), 0,1%
2. Mercury (Hg), 0,1%
3. Cadmium (Cd), 0,1%
4. hexavalent chromium (Cr VI), 0,1%
5. Polybrominated biphenyls (PBB), 0,1%
6. Polybrominated diphenyl ethers (PBDE), 0,1%

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<sup>2</sup> <https://echa.europa.eu/de/substances-restricted-under-reach>



In 2015, Delegated Directive (EU) 2015/863 added the following substances at the end of the transitional period on July 22, 2019:

1. Bis(2-ethylhexyl)phthalate (DEHP), 0,1%
2. Benzylbutylphthalate (BBP), 0,1%
3. Diputhylphthalate (DBP), 0,1%
4. Diisobutylphthalates (DIBP), 0,1%

The final layers applied by us do not contain any of the substances mentioned or do not exceed the limit values mentioned. We explicitly point out that this declaration only applies on the condition that the base materials selected by the customer for surface finishing also comply with the requirements of this guideline.

### **Dodd-Frank Act and Regulation (EU) 2017/821 (conflict minerals)**

The final layers we apply do not contain any so-called conflict minerals (tin, tantalum, tungsten and their ores and gold), nor do we import such substances.

### **Toxic Substances Control Act (TSCA)**

Since 2021, the EPA has imposed restrictions on the following persistent, bio accumulative and toxic chemicals, which are regulated by the TSCA:

1. Phenol, Isopropylphosphate (3:1) (PIP (3:1) CAS 68937-41-7 (total ban)
2. Decabromdiphenyl ether (DecaBDE) CAS 1163-19-5 (total ban)
3. 2,4,6-Tris (tert-butyl)phenol (2,4,6-TTBP) CAS 732-26 (limit = 0,3 % by weight)
4. Hexachlorobutadiene (HCBD) CAS 87-68-3 (total ban)
5. Pentachlorothiophenol (PCTP) CAS 133-49-3 (limit = 1 % by weight)

The final layers applied by us do not contain any of the listed substances.

### **Proposition 65**

Proposition 65 is a law in the US state of California that aims to protect the cleanliness of drinking water and the general health of people. It is intended to inform consumers about possible risks from carcinogenic and reprotoxic substances. The California Office of Environmental Health Hazard Assessment (OEHHA) publishes a list of over 900 substances that are classified as carcinogenic or reprotoxic. This list is revised and republished at least once a year.

It lists metals and compounds that we intend to apply in the surface-treated intermediate or final layers. In particular, these may be cobalt compounds, nickel and (its oxides). Occasionally, mineral oils are applied to final layers, e.g. to increase corrosion resistance. Consequently, a situational and product-specific approach must be taken in each case.

## Regulation (EU) 2017/745; Medical Device Regulation (MDR)


The regulation on medical devices is intended to improve the safety and quality of medical devices, harmonize the internal market and promote innovation.

As a surface finisher, we are not a manufacturer of a product. We coat or transform surfaces on a contract basis for so-called components and component groups. We do not know the respective intended use or the detailed exposure and functionality of such components and component groups. Consequently, we are only able to name the coating composition of the intermediate and final coating applied by us. Due to the unknown exposures of products, objects and mixtures, we cannot exclude the possibility that surface treatment systems are inadequate or that possible transformation products, such as metal oxides, are formed during the intended use of the (complex) objects. In order to be able to make a final concrete assessment, measurements and, if necessary, additional tests on the same must be arranged by the manufacturer.

Selzach, April 17, 2024



Tobias Moser, CEO



Marion Etzold, Head of quality and production