

Certificate of Compliance (CoC)

Company PACCOR Polska Sp. z o.o., Skierniewice Branch, 96-100 Skierniewice, ul. Mszczonowska 75/83 declares that the product:

PS (HIPS/GPPS/MB) SPITTOON WITH LID colored in white (article number E400120/108659)

comply with the following directives and regulations:

- ✓ REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC amended by REGULATION (EU) 2020/561 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 23 April 2020;
- ✓ Framework Regulation (EC) 1935/2004;
- ✓ Plastic materials: Commission Regulation (EU) No 10/2011 with all amendments up to Commission Regulation (EU) 2020/1245 of Septemer 2, 2020;
- ✓ EC directive 94/62, concerning heavy metals. The sum of concentration of the heavy metals: Cr(VI), Hg, Cd, and Pb does not exceed 100 ppm;
- ✓ Polish Parliamentary Act of August 25, 2006 with amendments (latest: Dz. U. of 2010, Nr.136. poz.914) with executive regulations;
- ✓ ISO 9001:2015 QUALITY MANAGEMENT SYSTEM;
- ✓ BRC Global Standard for Packaging Materials.

Storage conditions and guarantee period: The products should be stored inside buildings, in dry, cool, clean, shaded areas, protected from direct sunshine and far away from heating devices. Protected from a foreign smell. Temperature of the storage 10-40°C, RH<80%. Presuming above good store conditions, guarantee time for use: 1 year max from production date.

This declaration is valid for a period of five years from the date below. It should be renewed in all cases where the previous conformity is no longer ensured and in the case of changes in the production process and regulations.

Skierniewice, Monika Mikulska, 21.03.2023r

Q&H Manager

PACCOR Polska Sp. z o.o. Oddział w Skiemiewicach ul. Mszczonowska 75/83, 96-100 Skierniewice tel. 46 834 05 00, fax. 046 833 35 66

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