To Whom It May Concern

Riga (Latvia)

21/05/2026, No. MO-27.2026

Subject: Manufacturer's Statement regarding MagSorb-16 Magnetic Rack (Cat. No. BS-010601)

This letter responds to requests for a CE Declaration of Conformity covering the product MagSorb-16, Magnetic Rack for Manual Nucleic Acid Extraction (Cat. No. BS-010601), manufactured by company Biosan SIA, registered and operating address at Ratsupites iela 7 k-2, Riga, LV-1067, Latvia, hereinafter – *Manufacturer.*

CE marking under applicable European Union [EU] legislation, including in particular Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008, and other applicable EU harmonisation legislation, applies only to products falling within the scope of specific EU harmonisation legislation and is affixed by the manufacturer following the conformity assessment procedures laid down in that legislation. For products outside the scope of such legislation, neither EU nor Latvian national legislation establishes a formal procedure by which a manufacturer can issue a declaration with legal force equivalent to a CE Declaration of Conformity. Thus, in place of such a declaration, Biosan SIA issues the following manufacturer's statement.

Product description

MagSorb-16 is a passive laboratory accessory consisting of a polymer housing fitted with permanent magnets, holding up to sixteen tubes of 1.5 to 2.0 ml. It contains no electrical or electronic components, no powered or moving parts, and no software. Operation requires only manual placement of tubes by the user.

Intended purpose as defined by the Manufacturer

MagSorb-16 is placed on the market by Biosan SIA as a general-purpose laboratory accessory. It is not intended by the Manufacturer for use as a medical device within the meaning of Regulation (EU) 2017/745 or as an in vitro diagnostic medical device within the meaning of Regulation (EU) 2017/746. It is not supplied with a medical or diagnostic intended purpose, and it is not marketed as an accessory to any specific medical device or *in vitro* diagnostic medical device. The intended purpose and, where applicable, the CE marking of any reagent or kit used together with MagSorb-16 are defined by the respective reagent manufacturer.

EU harmonisation legislation

The product MagSorb-16 does not fall within the scope of the Low Voltage Directive 2014/35/EU, the Electromagnetic Compatibility Directive 2014/30/EU, the Machinery Directive 2006/42/EC, or the RoHS Directive 2011/65/EU, nor within the scope of any other EU harmonisation legislation providing for CE marking. The product contains no electrical circuitry, no driven moving parts, and is not electrical or electronic equipment within the meaning of those instruments. Accordingly, no CE Declaration of Conformity is issued for MagSorb-16, and the product does not bear the CE marking. Under Article 30(2) of Regulation (EC) No 765/2008, CE marking is not to be affixed to products outside the scope of EU harmonisation legislation that provides for such marking.

General Product Safety

MagSorb-16 is placed on the EU market in accordance with the General Product Safety Regulation (EU) 2023/988.

Status of this Statement

This document is the Manufacturer's statement issued by Biosan SIA on its own responsibility. It reflects the intended purpose of MagSorb-16, as defined by the Manufacturer, and the product's resulting regulatory position.
It is not a CE Declaration of Conformity and is not intended to substitute for one.

For further information, please contact marketing@biosan.lv.

Yours faithfully,

Sales and Marketing Director Andrejs Gaivoronskis
On the behalf of **Biosan SIA**