

«POLYMERCOM» SRL	Technical Internal Document	EC Declaration 02_2023
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«POLYMERCOM» SRL

EC Declaration of conformity

Manufacturer`s name - POLYMERCOM S.R.L.

Address/HQ – Republic of Moldova, Chisinau, 75 Nicolae Milescu-Spataru street;

Name and intended of the Device (s) - Plastic containers for stool collection;

Classification – **Class I**, on the basis of Rule 1, point 1.1 (**non-invasive devices**), (**non-sterile, non-reusable medical device**) of Annex IX (classification criteria) Chapter III (classification), in reference to Article 11 of the legislative decree of 24 February 1997 n.46 and subsequent and integrations;

Notified Body – Not applicable – non sterile Class I

Conformity assessment route –

- POLYMERCOM S.R.L. uses the following procedures for the CE-labeling of their products according the Regulation MDR 2017/745
- EC conformity declaration according to annex II + annex III

POLYMERCOM, the manufacturer of the medical device

DECLARES

Under his own responsibility:

- This declaration of conformity is issued under the sole responsibility of POLYMERCOM. We hereby declare that the medical device(s) specified above meet the provision of the Directive 2007/47/EC, remedial of Directive 93/42/EEC on medical devices;
- It undertakes to keep at the disposal of the Authority the technical dossier product (dated 01 November 2022), as specified in Annex VII to Directive 2007/47/EC, remedial of Directive 93/42/EEC of reference, for a period of at least five years after the last date of placing on the market of the last batch or serial number of devices indicated;

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- It accordingly declares that the device in question is in accordance with what described in Directive 2007/47/EC, remedial of Directive 93/42/EEC and additionally, this declaration is supported by the Health Certificate. This certificate confirms the production, use and sale of the intended medical device - Plastic containers for stool collection and comply with the Sanitary Regulations DT MD 83-38286648-005:2017, SM EN ISO 24998:2016, HG 278/2013, HG 102/2017.

Chisinau, MAY 03, 2023

Technical and Regulatory Director
PAPUSOI Oleg