



EURO IMPACT S.R.L.

VAT No. RO 13881247 | Trade Register No.: J2001000283246

Registered office: 698 Ruscova Village, Maramureş County, PC 437260, Romania

Work point: 772 Leordina, Maramureş County, Romania

Phone: +40 783016964/+40 730336088,

e-mail: office@ask4mask.ro site web: www.ask4mask.ro

EU DECLARATION OF CONFORMITY

Device Name / Type	Reference No.	Basic UDI-DI	UDI-DI
Medical mask ASK4MASK, Type IIR, 50 pcs	ASK4MASK-50-ALBASTRU	5944759047ASK4MASKEING	5944759047006
Medical mask ASK4MASK, Type IIR, 5 pcs	ASK4MASK-5-ALBASTRU	594475904759047EIFF	5944759047013
Medical mask ASK4MASK, Type IIR, 50 pcs	ASK4MASK-50-ROZ	59447590475944759047ROZGO	5944759047020

*ALBASTRU = BLUE

*ROZ = PINK

Type : IIR

Brand : ASK4MASK

Manufacturer : SC EURO IMPACT SRL

SRN No : RO-MF-000021106

Manufacturer Address:

Registered office: 698 Main Street, Ruscova Village, Maramureş County, postal code 437260, Romania

Work point: 772 Principal Street, Leordina, Maramureş County, postal code 437180, Romania

Intended Purpose and Regulatory Information

The intended use of the medical device is to limit the transmission of infectious agents (viruses, bacteria, fungi) from healthcare personnel to patients during surgical procedures and in other medical environments with similar requirements.

Classification

Class I, according to Rule 1 of Annex VIII of Regulation (EU) 2017/745 on medical devices.

We declare under our sole responsibility that the above-mentioned product meets the regulatory requirements of Regulation (EU) 2017/745 (MDR) of 26 May 2021 on 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.

We undertake to retain and make available to the competent authorities all documentation relating to the product for a period of at least 10 years from the last date of manufacture.

Applicable Standards: The product is designed and manufactured under a Quality Management System in accordance with ISO 13485:2016 and tested in accordance with EN 14683:2019+AC:2019 for Type IIR medical masks.

Tested in accordance with ISO 22609:2004 for resistance to synthetic fluid penetration (Splash Resistance).

Place and Date of Issue of the Declaration of Conformity: 30.06.2022

This declaration is issued under the sole responsibility of the manufacturer.

Responsible for this declaration,

on behalf of S.C. EURO IMPACT S.R.L.

General Manager

Mr. Simion Pop

