



FEDERAL STATE UNITARY ENTERPRISE
"KHRUNICHEV STATE RESEARCH and PRODUCTION SPACE CENTER"
MEDICAL EQUIPMENT AND CONSUMER GOODS DIVISION
(ME & CGD)

DECLARATION OF CONFORMITY
Medical Devices Manufacturer

Enterprise: FSUE Khrunichev State Research & Production Space Center,
Medical Equipment & Consumer Goods Division

Address: 18, Novozavodskaya, 121309, Moscow, Russia
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hereby declares that:

1 The Enterprise certifies that development and production of medical product BLKS-303MK MONOPLACE HYPERBARIC THERAPY SISTEM, to be applied in hyperbaric oxygenation medical treatment with maximum overpressure 0,3 MPa (3 Bar), established in compliance with acting Russian laws and EC international norms, do not infringe any patent, trade mark, commercial secret or any other ownership right or any relevant right of any third party.

2 The enterprise observes the requirements of COUNCIL DIRECTIVE 93/42/EEC and other European Community regulatory documents on medical devices produced in batch.

3 The Enterprise intends to plan and carry out, in a successive order, measures referred to improve and effectively operate the quality management system in compliance with the requirements of ISO 9001:2008, EN ISO 13485:2003 international standards. The Enterprise has been aware of the notified bodies to provide within their own competence from time to time control of acting quality management system established to manufacture quality, efficiency and operation safety of medical devices in compliance with European laws.

O.A. Posypkin,

Director

Medical Equipment & Consumer Goods Division
FSUE Khrunichev State Research & Production Space Center

