Declaration of Conformity (DoC)

Manufacturer Name:	Medifactia AB
Manufacturer Address:	Medifactia AB c/o IOFFICE BUSINESS CENTER Kungsgatan 60 111 22 Stockholm SWEDEN
Telephone Number:	+46 (0)8-460 072 06
E-mail Address:	info@medifactia.com
Product:	Transit-Pellets
UDI/Art. No.:	0 7350099 55001 0
Classification:	IIa according to Rule 5 LVFS 2003:11 Appendix 9

We hereby declare the medical devices specified above conform with the essential requirements listed in Annex 1 and meet the provisions stated in SFS 1993:584, Annex V of the MDD 93/42/EEC as amended by 2007/47/EC (LVFS 2003:11 as amended in LVFS 2009:18). This declaration is supported by the Quality Management System in accordance to Annex V and VII in MDD 93/42/EEC.

Standards Applied

ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes
ISO 10993-1:2018 – Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process.
EN ISO 14971:2019 – Medical Devices – Application of risk management to Medical Devices.
EN ISO 15223:2016 – Medical Devices – Symbols to be used with the Medical Device labels, labelling and information to be supplied – Part 1: General requirements.
EN 1041:2008 + A1 2013 – EN 1041:2008 + A1 2013

Notified Body and Identification Number	Research Institutes of Sweden AB (RISE), 0402
EC Certificate Number	SC0557-15
Start of CE Marking	2016-05-17

Signature: Oisin Mystrom, CEO
(name, function)

Place and Date of issue: Stockholm 21.09.01