



DECLARATION OF CONFORMITY

MANUFACTURER	M.&G. INT.'L SRL			
SRN	IT-MF-000033577			
PRODUCT	BIO 101	BIO 102	BIO 103	BIO 104
CLASS	IVD, CLASS A			
DESCRIPTION	Isothermal bags for biological samples transport			
BASIC UDI	803397694BIONQ			

We, M.&G. INT.'L SRL, with headquarters in Via Manzoni 20 – 20838 Renate (Italy) declare under our sole responsibility that the products **BIO 101, BIO 102, BIO 103, BIO 104** to which this declaration relates are in conformity with the following standard(s) or other normative document(s):

- ✓ **Regulation (EU) 2017/746**
- ✓ **ISO 14971**
- ✓ **ISO 15223-1**

Furthermore, M.&G. INT.'L SRL has implemented and maintains a quality management system which complies with the following standards:

- ✓ **ISO 9001:2015**
- ✓ **ISO 13485:2016**
- ❖ The medical devices to which this declaration relates are sold in a non-sterile packaging.
- ❖ Any changes made to the medical device not authorized by M.&G. INT.'L SRL nullify the validity of this declaration.

Renate, 24th February 2023

Rossana Molteni

Legal Representative

M. & G. INT.'L s.r.l.
Via Manzoni, 20 - 20838 RENATE
Cod. Fisc. e P. IVA 05041920967

M. & G. INT.'L SRL

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