DECLARATION OF CONFORMITY

1 Manufacturer

SanoMed Manufacturing bv
Address: Transportweg 13-001
       4501PS Oostburg
       The Netherlands

SRN: NL-MF-000002684

2 Product(s) (name, type or model):

- SanoSkin OXY 30 gram
- Melladerm Plus 20 gram
- Melladerm Plus 50 gram
- Melloxy 20 gram
- Melloxy 50 gram
see appendix

3 The product(s) described above is in conformity with:

Title	Document No.
Medical Device Regulation	(EU) 2017/745

4 Additional information (conformity procedure, Notified Body, CE certificate, etc.):

Conformity assessment procedure: Medical Device Regulation, **Annex IX without Chapter II**.
Notified Body: KIWA NB-no: 0476   CE-certificate nr. : *MDR 00029-A (expiry 2029/05/05)*

This Declaration of Conformity is issued under the sole responsibility of the manufacturer:

Oostburg   2024/05/23   Jan Vandeputte, CEO
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(Place & date of issue (yyyy-mm-dd))   (name; function and signature of manufacturer)

Declaration form: Standard ISO/IEC 17050-1:2010

Appendix

Date: 2024- 05 - 24

List of devices

Product name	Trade name	Product code/ catalogue number/ unambiguous ref.	Intended purpose	Risk class/ rule[1]	Basic UDI-DI[2]	UDI-DI	First date of CE-compliance
SanoSkin OXY	SanoSkin OXY 30 gram	OX30	Wound treatment	IIb rule 4	871775519OX4M	8717755190581	2008/07/30
Melladerm Plus	Melladerm Plus 20 gram	MDP20	Wound treatment	IIb rule 4	87177519MDPTK	8717755190604	2008/07/30
Melladerm Plus	Melladerm Plus 50 gram	MDP50	Wound treatment	IIb rule 4	87177519MDPTK	8717755190628	2008/07/30
Melloxy	Melloxy 20 gram	MO20	Wound treatment	IIB rule 4	87177519MO3V	8717755190642	2008/07/30
Melloxy	Melloxy 50 gram	MO50	Wound treatment	IIB rule 4	87177519MO3V	8717755190666	2008/07/30

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[1] See risk classification in Medical Device Regulation, annex VIII

[2] Product and trade name, product code, catalogue number or other unambiguous reference allowing identification and traceability of the device covered by the EU declaration of conformity, such as a photograph, where appropriate, as well as its intended purpose. Except for the product or trade name, the information allowing identification and traceability may be provided by the Basic UDI-DI