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Approver Rune Nystad	Approval date 2024-11-11

EU Declaration of Conformity

Company name: Observe Medical AB
SRN: SE-MF-000017468
Postal address: Krokslätts Parkgata 4
Postcode, city, and country: 431 68 Mölndal, Sweden

Medical device of concern:	REF:	Basic UDI-DI:
UnoMeter™ Safeti Plus	1710085	0735005767400U9
	1710086	
	1710087	
	1710088	
	1710089	
	1710090	

Risk classification: Is, Im, MDR Rule 1, Annex VIII

We, Observe Medical AB, hereby certify that the medical device covered by this Declaration of Conformity is in conformity with the following relevant Union legislation(s):

MDR: Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices

Relevant harmonized standards used, any CS or other technical specifications in relation to which conformity is declared is referred to in the General Safety and Performance Requirements Checklist:

Document ID: PMF-0795 GSPR UnoMeter Safeti Plus

Name and identification number of the Notified body:

Intertek Medical Notified Body
Notified Body identification number: 2862

Conformity assessment based on a Quality Management System and on assessment of Technical documentation, procedure according to Annex IX.

EC Certificate number: 28620123041

This declaration of conformity is issued under the sole responsibility of the manufacturer Observe Medical AB.

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This Declaration of Conformity is electronically signed by:

Rune Nystad,

PRRC, Observe Medical AB

Approval date (see page 1)