EU Declaration of Conformity (DoC)

This Declaration of Conformity is issued under the sole responsibility of the Diversey Europe Operations B.V.

MANUFACTURER		
Name of Company	**Address**	**SRN**
Diversey Europe Operations B.V.	Maarssenbroeksedijk 2 3542 DN Utrecht, The Netherlands	NL-MF-000006623

Intended use: Oxivir family products are intended to be used as cleaners and disinfectants on non-invasive medical devices.

PRODUCT IDENTIFICATION		
Product Name	**Reference number /SKU**	**Basic UDI-DI**
Oxivir Plus	100826547 100832563 100827422 101106427 101106835 100827424 101106428 101104581	8720938285OxivirPlus7C
Oxivir Plus Spray	100837681 101106823 100829235 100829234 100929512 101104583	
Oxivir CE Plus	100827454	
Oxivir CE Plus Spray	100829237	
Oxivir Plus J-flex	101106726 100948466 100829921 100829789	

Oxivir Excel	101103926 101104582 101105168 101105291 101105904 100941436 100968158	8720938285OxivirExcelS7
Oxivir Excel CE	100941438	
Oxivir Ecxel Foam	101103967 101103966 101104584 100941562 100941433 100941434 100941432 100966872 100957194 603057	
Oxivir Excel Foam CE	100941563 100976019	
Oxivir Excel Wipe	603055 100984246 100984247 100984248 100984250	
Oxivir Excel Wipe CE	100984249	
Oxivir Sporicide	100941748 101105889 100934091 100981226 101104576	8720938285OxivirSpor7Z
Oxivir Sporicide CE	100959788 100959786	

Oxivir Sporicide Wipe	100941921 100941883 100941885 101105190 101105890	
Oxivir Sporicide Wipe CE	100959787	

CONFORMITY ASSESSMENT		
Device Family	**Conformity assessment procedure description**	**CE certificate number**
Oxivir Excel, Sporicide and Plus	Annex II (without section 4) of the directive93/42/EEC	44232191507
		44232191507-EU MDR-Art 120 Extension letter

Device Classification: Class IIa, rule 15 according to Annex IX of MDD

Statement of conformity: We declare under our sole responsibility that Medical Devices covered under this declaration of conformity are in accordance with Annex I of requirements mentioned under the Medical Device Directive 93/42/EEC of June 14, 1993, and of its transpositions in member states national legislation. The products are designed fully under Diversey's Quality Management System based on EN ISO 13485:2016/A11:2021

EU Notified body: TUV Nord CERT GmbH.

Notified body ID: 0044

Person Responsible for Regulatory Compliance:

Name	**Edwin Baars**
Function	Executive Director GTS & Regulatory Europe & Person Responsible for Regulatory Compliance
Place and Date	Utrecht, 9-07-2024

Signature	