AUTHORISATION NUMBER: **IE/BPA 70471**

EUROPEAN COMMUNITIES (AUTHORISATION, PLACING ON THE MARKET, USE AND CONTROL OF BIOCIDAL PRODUCTS) REGULATIONS

CERTIFICATE OF AUTHORISATION

The Competent Authority for Biocides in Ireland, pursuant to the provisions of Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products, as amended by Regulation (EU) No 334/2014, and European Union (Biocidal Products) Regulations, 2013, (S.I. 427 of 2013), grants authorisation to make available on the market in Ireland, the biocidal product:

Biocidal Product Family Name:	Clinitex Hard Surface Disinfection Wipes	
Name and address of the authorisation holder	**Name**	Staphyt Regulatory SAS
	Address	23 Rue de Moeuvres, Inchy-en-Artois 62860 France
Authorisation number	IE/BPA 70471	
Authorisation type	Mutual recognition in parallel (NA-MRP)	
Date of the authorisation	22nd March 2019	
Expiry date of the authorisation	28th February 2029	

subject to the conditions detailed in the Annexes to this certificate.

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Authorisation granted on behalf of the Competent Authority for Biocides in Ireland by

Louise Pierse

Pesticide Control Division (PCD)

Official Stamp:

Version: 1.6

ANNEX I

Product Family Summary and Conditions of Authorisation

Biocidal Product Name	Clinitex Hard Surface Disinfection Wipes IE/BPA 70471
Additional Trade names (with suffixes to the Authorisation number)	Homecare Hard Surface Wet Wipes – IE/BPA 70471-001 Spearhead Hard Surface Disinfection Wipes – IE/BPA 70471-002 Beaucare Medical Supreme Hard Surface Wipes – IE/BPA 70471-003 Klentex Professional Hard Surface Disinfection Wipes – IE/BPA 70471-004 Surfol Maxi Alcohol Surface Wipes – IE/BPA 70471-005 Clinitex Blue Hard Surface Disinfection Wipes – IE/BPA 70471-006 Protect + Hard Surface Disinfection Wipes – IE/BPA 70471-007 Mediclean Hard Surface Disinfection Wipes – IE/BPA 70471-008 Klenzeen A Wipe – IE/BPA 70471-009 Excedo Moist Disinfection Wipes – IE/BPA 70471-010 Clinicept 70% IPA Wipes – IE/BPA 70471-011 Mediteq Healthcare Solutions Hard Surface Disinfection Wipes – IE/BPA 70471-012
R4BP asset number	IE-0020385-0000
Marketing Company, Address	To be confirmed

Active Substance(s) (% w/w):	Propan-2-ol (70% W/W)
Product-Type:	PT 02 (Disinfects and algaecides not intended for direct application to humans or animals)
Product Composition:	See Confidential PAR on R4BP3
Substance(s) of Concern:	N/A
Comparative Assessment	NO
Formulation Type:	Other: Wipes
Area of Use:	Indoor use
Statement of use:	This product is indoor use for the disinfection of small areas of hard surface (door handles, cabinets, tables, worktops, etc.) and equipment (general equipment including telephones, trolleys, etc.) in care homes, hospitals and laboratories (medical area).
User Category:	Professional Trained Professional

Special labelling provisions for Ireland:	In addition to the details recorded on the SPC, the following details shall be recorded on the product label(s). **Use Biocides Safely and Sustainably** **It is illegal to use this product for uses or in a manner other than that prescribed on this label.** **Poison Information:** For information or to report a poisoning incident contact **The National Poisons Information Centre, Beaumont Hospital, Dublin (01-8092166)**, retain the label for reference.

This authorisation may be subject to review in accordance with Regulation (EU) No 528/2012, as amended by Regulation (EU) No 334/2014, or the European Union (Biocidal Products) Regulations, 2013, (S.I. 427 of 2013). The outcome of such a review may lead to amendments to or the revocation of this authorisation.

The following conditions and restrictions apply:

1. Product may **not** be made available on the market or used in the Republic of Ireland unless it complies with the Annexes of this authorisation.

2. The requirements and conditions, specified in the Annexes, of this authorisation may **not** be altered without prior approval of modifications by the Irish Competent Authority for Biocides in Ireland. Where any amendments are made to the original authorisation in another Member State, the Irish Competent Authority for Biocides in Ireland must be informed by the Authorisation Holder.

3. The holder of this certificate for authorisation must inform or provide the Irish Competent Authority for Biocides with any new or requested information/data, respectively, that shows this biocidal product and/or any of its active substances cause or may cause an adverse effect on human or animal health, ground water or the environment.

4. All product made available on the market in Ireland must comply with the classification, labelling and packaging requirements established in: Article 69 of Regulation (EU) No 528/2012; the Chemicals Act 2008 (as amended) transposing Regulation (EC) No 1272/2008; and the classification, labelling and Safety Data Sheet information detailed in the Annex II to this certificate.

5. All biocidal products advertised must comply with Article 72 of Regulation (EU) No 528/2012.

6. A printed copy of the Irish label in accordance with the Annexes of this authorisation must be submitted to the Irish Competent Authority for Biocides prior to any product being made available on the market in Ireland. All product labels must carry the authorisation number of the form: IE/BPA 70471.

7. Safety Data Sheets (SDS) for the biocidal product(s) shall be prepared and made available in accordance with Article 70 of the Biocidal Products Regulation 528/2012 (as amended). Relevant sections of the SDS must be updated post-authorisation in accordance with Annex II of the authorisation certificate. In particular, Section 15 of the SDS should be updated to contain the authorisation number IE/BPA 70471. The SDS must be submitted to the Irish Competent Authority for Biocides and the National Poisons Information Centre

of Ireland http://www.poisons.ie/manufacturers.asp before the product is made available on the market for sale or use.

8. On an annual basis, details of the quantities of this product (by pack size) manufactured in Ireland, imported into Ireland and/or exported from Ireland must be submitted to the Irish Competent Authority for Biocides by 31 January of the following year.

9. **Fees are payable for the maintenance of the product on the Register of Biocidal Products and shall be paid by the 31st December of the following year and each year thereafter.**

(b) Amendments to Authorisation

The following amendments apply to the conditions of authorisation for the biocidal product family:

Issue	Re-issue	Version	Modifications applied[2]
22/03/2019	-	1.0	Original certificate
-	11/03/2020	1.1	NA-ADC – additional trade names
-	18/03/2020	1.2	NA-ADC – Addition of a manufacturer
-	22/12/2020	1.3	Transfer of national authorisation
-	20/09/2021	1.4	Update of expiry date to match original authorisation
-	22/03/2023	1.5	NA-ADC Additional AS manufacturer BC-SB075888-21
-	26/09/2023	1.6	NA-ADC Additional trade name BC-XY084986-71

ANNEX II

Summary of Product Characteristics (SPC) for a biocidal product family

The following conditions, outlined in the summary of product characteristics (SPC), apply to the authorisation for the biocidal product family as provided for in Article 22 of Regulation (EU) No 528/2012 as amended. The authorised biocidal product family SPC file is referenced below:

Issue	Re-issue	Version	File Name
22/03/2019	-	1.0	spc_Clinitex Hard Surface Disinfection Wipes_IE_en_201903111445
-	11/03/2020	1.1	spc_Clinitex Hard Surface Disinfection Wipes_IE_en_202003110848
-	18/03/2020	1.2	spc_Clinitex Hard Surface Disinfection Wipes_IE_en_202003181128
-	22/12/2020	1.3	spc_Clinitex Hard Surface Disinfection Wipes_IE_en_202012211411
-	20/09/2021	1.4	spc_Clinitex Hard Surface Disinfection Wipes_IE_en_202012211411
-	22/03/2023	1.5	spc_Clinitex_Hard_Surface_Disinfection_Wipes_IE_en_202205191613
-	26/09/2023	1.6	spc_Clinitex_Hard_Surface_Disinfection_Wipes_IE_en_202303010843