



Diversey Europe BV

Certificate of Analysis

Date 29.04.2025
Purchase order item/date 4500285343 / 26.09.2024
Delivery item 88055552 900001
Order item/date 4448268 000010 / 26.09.2024
Customer number 5215646

Company
Henri Essers en Zonen Internationaa
Transport NV
Henry Fordlaan 8
3600 GENK
BELGIUM

Repeat printout

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Article

70001369 ClearKlens Oxifast -sterile- 1 l FL

Batch: 1616073

Expiry Date: 2026/09

Date of manufacture: 30/09/2024

Characteristic Method	Unit	Value	Lower Limit	Upper Limit	Conformity
peracetic acid MAN LCQ 011	%	0,10	0,07	0,10	Yes
Hydrogen peroxide MAN LCQ 011	%	3,05	2,90	3,40	Yes
loss OAT 16h at 96 ° C MAN LCQ 009	%	0,31	0,00	2,50	Yes
stérility certificate european pharmacopea 2.6.1			conform		Yes

released on: 21/03/2025 by: DEPREZ

Comments:

The analysis results above could change over time and in function of the storage temperature. It is imperative to store the products according to the recommended conditions indicated in the MSDS.

This certificate of analysis has been printed through an EDP-System and is therefore unsigned.

*** End of certificate of analysis ***

CERTIFICATE OF STERILITY

BIOXAL

ZI Sud – Secteur A
Route des Varennes
71100 CHALON / SAONE
FRANCE,

Certifies that the product:

CLEARKLENS OXIFAST STERILE 1L
Item code: 70001369
Batch number: SEP/1616073/24/274
Quantity: 288 bottles,

is sterile, according to sterility test Ph.Eur. 2.6.1.

Alicia DEPRez

BIOXAL Quality Manager



IONISOS- Dagneux
176 ROUTE DE BALAN
Parc Dombes Cotières Activités
01120 DAGNEUX
France

Client
BIOXAL
BIOXAL
Zone Industrielle Sud - Secteur A
Route des Varennes
FR-71100 CHALON-SUR-SAÔNE
France

Rayonnement Gamma Treatment Certificate

Sales Order No.: 240003369

Client Sales Ref.: 4500282833 - SCHULKE 4500282795

Item Reference: DAG-0000514 QP RUN 1 -CLEARLENs OXIFAST VH49

Quantity Treated: 9 Carton(s)

Treatment Reference:
000DAGC1A21: / PQ source 2024 - N°240003369

Treatment Information:
GR-25-000001102 of 20/01/25

Client Batch - Comments:
QP RUN 1-1616073

Client Request:
Dose minimum value 15.0 KiloGray
Dose maximum value 28.0 KiloGray

Certificate Type:
MIN/MAX Read: Minimum and maximum doses read at the control points.

Uncertainty:
The 4% dosimetric uncertainty is included in the expected doses.

Control point Reference	Expected Minimum dose kGy	Result Minimum dose kGy	Expected Maximum dose kGy	Result Maximum dose kGy
R	17.0	18.0	22.3	18.0

Treatment controlled by
DAG- Véronique CASTANIER
DAG-Quality services
Le 05/02/25 à 12:33:49
Certificate was electronically signed

IONISOS- Dagneux
176 ROUTE DE BALAN
Parc Dombes Cotières Activités
01120 DAGNEUX
France

Client
BIOXAL
BIOXAL
Zone Industrielle Sud - Secteur A
Route des Varennes
FR-71100 CHALON-SUR-SAÔNE
France

Rayonnement Gamma Treatment Certificate

Sales Order No.: 240003369

Client Sales Ref.: 4500282833 - SCHULKE 4500282795

Item Reference: DAG-0000514 QP RUN 2 -CLEARLENDS OXIFAST VH49

Quantity Treated: 9 Carton(s)

Treatment Reference:
000DAGC1A21: / PQ source 2024 - N°240003369

Treatment Information:
GR-25-000001103 of 20/01/25

Client Batch - Comments:
QP RUN 2-1616073

Client Request:
Dose minimum value 15.0 KiloGray
Dose maximum value 28.0 KiloGray

Certificate Type:
MIN/MAX Read: Minimum and maximum doses read at the control points.

Uncertainty:
The 4% dosimetric uncertainty is included in the expected doses.

Control point Reference	Expected Minimum dose kGy	Result Minimum dose kGy	Expected Maximum dose kGy	Result Maximum dose kGy
R	17.0	17.8	22.3	17.8

Treatment controlled by
DAG- Véronique CASTANIER
DAG-Quality services
Le 05/02/25 à 12:33:50
Certificate was electronically signed

IONISOS- Dagneux
176 ROUTE DE BALAN
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01120 DAGNEUX
France

Client
BIOXAL
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Route des Varennes
FR-71100 CHALON-SUR-SAÔNE
France

Rayonnement Gamma Treatment Certificate

Sales Order No.: 240003369

Client Sales Ref.: 4500282833 - SCHULKE 4500282795

Item Reference: DAG-0000514 QP RUN 3 -CLEARKLENS OXIFAST VH49

Quantity Treated: 9 Carton(s)

Treatment Reference:
000DAGC1A21: / PQ source 2024 - N°240003369

Treatment Information:
GR-25-000001104 of 20/01/25

Client Batch - Comments:
QP RUN 3-1616073

Client Request:
Dose minimum value 15.0 KiloGray
Dose maximum value 28.0 KiloGray

Certificate Type:
MIN/MAX Read: Minimum and maximum doses read at the control points.

Uncertainty:
The 4% dosimetric uncertainty is included in the expected doses.

Control point Reference	Expected Minimum dose kGy	Result Minimum dose kGy	Expected Maximum dose kGy	Result Maximum dose kGy
R	17.0	17.9	22.3	17.9

Treatment controlled by
DAG- Véronique CASTANIER
DAG-Quality services
Le 05/02/25 à 12:33:50
Certificate was electronically signed

IONISOS- Dagneux
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Parc Dombes Cotières Activités
01120 DAGNEUX
France

Client
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Route des Varennes
FR-71100 CHALON-SUR-SAÔNE
France

Rayonnement Gamma Treatment Certificate

Sales Order No.: 240003369

Client Sales Ref.: 4500282833 - SCHULKE 4500282795

Item Reference: DAG-0000514 CLEARLENDS OXIFAST VH49

Quantity Treated: 9 Carton(s)

Treatment Reference:
000DAGC1A21: / PQ source 2024 - N°240003369

Treatment Information:
GR-25-000001105 of 20/01/25

Client Batch - Comments:
1616073

Client Request:
Dose minimum value 15.0 KiloGray
Dose maximum value 28.0 KiloGray

Certificate Type:
MIN/MAX Read: Minimum and maximum doses read at the control points.

Uncertainty:
The 4% dosimetric uncertainty is included in the expected doses.

Control point Reference	Expected Minimum dose kGy	Result Minimum dose kGy	Expected Maximum dose kGy	Result Maximum dose kGy
R	17.0	17.7	22.3	17.7

Treatment controlled by
DAG- Véronique CASTANIER
DAG-Quality services
Le 05/02/25 à 12:33:50
Certificate was electronically signed

Labor LS SE & Co. KG | Mangelsfeld 4, 5, 6 | 97708 Bad Bocklet | Germany
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71100 CHALON SUR SAÔNE
FRANKREICH

Fon: +49 (0)97 08/91 00-0
labor@labor-ls.de
www.labor-ls.de

Bad Bocklet 18 Mar 2025 / LÜ / BIOXCh

Certificate of Analysis

LS No:	250227-0122-001	LS Code:	2771774 / S
Product name:	Clearklens oxifast sterile 1L		
Lot No:	1616073		
Description:	2026/09		
Subject of test:	Liquid		
Entry temperature:	Room Temperature		
Your Order No:	4500286490		
Order dated:	26 Feb 2025	Sample receipt:	27 Feb 2025
Start of test:	04 Mar 2025	End of test:	18 Mar 2025

Test for Sterility on "ClearKlens Oxifast, 8 samples à 1 L"

Testing according to: Ph. Eur. 2.6.1. (11.6)
USP-NF <71> (2024, Issue 3)

Parameter	Specification / Demands	Result
Reference Document:	Growth Promotion Test (241115-0074-001) on "Clearklens Oxifast sterile 1l" (No product specific suitability test or method transfer existent)	
Test Method:	Membrane Filtration	
Test Environment:	Clean Room	
No. of tested Samples:	8 unit(s)	8 unit(s)
Tested Volume per Sample:	100 ml	100 ml
Type of Filter Material:	PVDF (Durapore®)	PVDF (Durapore®)
Test System:		TZHVLV210 (PVDF)
Culture Media:	TSB & FTM with neutralization agents (C+/T+)	C+/T+
Volume of used Culture Media:	100 ml	100 ml
Start of Incubation:		04 Mar 2025
End of Incubation:		18 Mar 2025
Incubation period:	At least 14 days	14 days
Evaluation:	No macroscopic growth visible	complies

The test was conducted in compliance with GMP guidelines. There were no test-related deviations.
This document was created by a GMP-supervised LIMS and approved by electronic signature.

Approved on 18 Mar 2025 at 13:08 by Olivia Halamoda, Specialist Manager.