



DECLARACIÓN DE CONFORMIDAD DECLARATION OF CONFORMITY

REGLAMENTO (UE) No 528/2012 DEL PARLAMENTO EUROPEO Y DEL CONSEJO
REGULATION (EU) No 528/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

**FABRICANTE:
MANUFACTURER**

C.V. MEDICA, S.L.



**DIRECCIÓN:
ADDRESS**

POLÍGONO INDUSTRIAL "LA PLANA" C/ PONENT, 1.
43424. SARRAL – TARRAGONA (SPAIN).

NOMBRE DE PRODUCTO / PRODUCT NAME:

CEPILLO/ESPONJA CON DIGLUCONATO DE CLORHEXIDINA 4% ESPONJA CON DIGLUCONATO DE CLORHEXIDINA 4%
SCRUB/SPONGE WITH CHLORHEXIDINE DIGLUCONATE 4% SPONGE WITH CHLORHEXIDINE DIGLUCONATE 4%

(Referencias en Anexo I) / (References on annex I)

MARCA / BRAND:

DISPOSCRUB C / DISPOSCRUB C SPONGE



**FINALIDAD PREVISTA:
INTENDED USE**

Cepillo/Espónja impregnado con digluconato de clorhexidina para un solo uso, lavado antiséptico de piel intacta para uso prequirúrgico.

Scrub brush/Sponge with chlorhexidine digluconate for single use, antiseptic washes for intact skin for pre-surgical use.

**CUMPLE LOS REQUISITOS:
CONFORMS WITH THE REQUISITES:**

Regulation (EU) No 528/2012	relativo a la comercialización y el uso de los biocidas <i>concerning the making available on the market and use of biocidal products</i>
EN 13624:2014	Antisépticos y desinfectantes químicos. Ensayo cuantitativo de suspensión para la evaluación de la actividad fungicida o levuricida en medicina. Método de ensayo y requisitos (fase 2, etapa 1). <i>Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area - Test method and requirements (phase 2, step 1).</i>
EN 13727:2012+A2:2015	Antisépticos y desinfectantes químicos. Ensayo cuantitativo de suspensión para la evaluación de la actividad bactericida en el área médica. Método de ensayo y requisitos (fase 2, etapa 1). <i>Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity in the medical area - Test method and requirements (phase 2, step 1)</i>
EN 12791:2006	Antisépticos y desinfectantes químicos. Desinfección quirúrgica de las manos. Requisitos y métodos de ensayo (fase 2/etapa 2). <i>Chemical disinfectants and antiseptics - Surgical hand disinfection - Test method and requirement (phase 2/step 2)</i>
EN 1499:2013	Antisépticos y desinfectantes químicos. Lavado higiénico de las manos. Método de ensayo y requisitos (fase 2/etapa 2). <i>Chemical disinfectants and antiseptics - Hygienic handwash - Test method and requirements (phase 2/step 2)</i>

Firmado <i>Signed:</i>	  C.V. MEDICA, SL Pol. Ind. La Plana, c/ Ponent, 1 43424 SARRAL - Tarragona - Spain
Nombre <i>Name:</i>	Laura Cobo Homs
Cargo: <i>Function</i>	Representante Legal <i>Legal representative</i>
LUGAR Y FECHA DE EMISIÓN: <i>PLACE AND ISSUING DATE</i>	Sarral (Tarragona). 27 de noviembre de 2023 / November 27 th , 2023

ANEXO I / ANNEX I

LISTADO DE REFERENCIAS / LIST OF REFERENCES

CEPILLO/ESPONJA CON DIGLUCONATO DE CLORHEXIDINA 4%
SCRUB/SPONGE WITH CHLORHEXIDINE DIGLUCONATE 4%

REF.
0030230
0030230B
0030230C
0030230D
0030230E
0030230F
0030230G
0030230H
0030230i
0030230J
0030230K
0030230L
0030230M
0030230N
0030230P
0030230Q

ESPONJA CON DIGLUCONATO DE CLORHEXIDINA 4%
SPONGE WITH CHLORHEXIDINE DIGLUCONATE 4%

REF.
0030330
0030330B
0030330C
0030330D
0030330E

Disposcrub C 4% CLX

Surgical brush with sponge containing 4% chlorhexidine digluconate. Indicated for surgical disinfection of hands of technical healthcare personnel. Only for healthy skin. Not reusable.

Size

80x50x37 mm. ± 2.5 mm.

Composition

4% Chlorhexidine Digluconate (20 ml)

Utility

Surgical washing of hands and nails of technical-health personnel.

Use our [metal bracket](#) to fix the 30-piece toothbrush dispenser to the wall.

Applications



Reduced mobility



Suitable for general use



DISPOSCRUB C

SCRUB BRUSH with 4% chlorhexidine digluconate antiseptic for healthy skin-biocide for human hygiene

COMPOSITION Scrub brush with antiseptic soap: Chlorhexidine Digluconate 4 g, Propan-2-ol 3.9 g, Citric acid monohydrate 1.5 g, Excipients q.s. 100 g

PURPOSE Antiseptic wash and surgical scrub. Does not affect the pH of the skin.

INSTRUCTIONS:

Wet hands and forearms, apply the product with the scrub brush and rub for 1 minute. Rinse with water and dry with hot air or a disposable towel. Use the nail cleaner for difficult access zones.

Store at a temperature between 5° and 30°C.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE

For external use. Do not ingest. Do not apply to broken skin. Avoid contact with eyes, mucous membranes and sensitive or diseased areas of skin. May cause skin or allergic reactions. Causes serious eye damage. IF IN EYES Rinse carefully with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing. Do not use in persons sensitive to any of the components, on extensive areas of skin, for prolonged periods of time or with non-breathable fabrics. Do not use in newborn infants. Use with caution in children under 2 years old. May cause chemical burns to the skin. Keep out of the reach of children. IN CASE OF INTOXICATION OR ACCIDENTAL INGESTION, call a POISON CENTRE, Tel: +34 91 562 04 20, or a doctor. To avoid risks to people and protect the environment, follow the instructions for use. Highly toxic to aquatic life. Toxic to aquatic life with long lasting effects. Avoid release to the environment. Collect spillage. Dispose of container in accordance with local regulations. Discard after use.

PHYSICAL AND CHEMICAL PROPERTIES:

Appearance: liquid Colour: pink Density: 1.02 ± 0.01 g/ml

DIMENSIONS OF PRODUCT UNIT:

80x50x37 mm. ±2.5 mm



PRESENTATION				
REFERENCE	DESCRIPTION	UNITS/BOX	BOX MEASUREMENTS (cm)	BOX WEIGHT* (kg)
0030230F	DISPOSCRUB C WITH CHLORHEXIDINE	100	38 x 21 x 35	3.5
0030230H	DISPOSCRUB C WITH CHLORHEXIDINE 15 dispensers of 30 units	450	60 x 39.5 x 50.5 (dispenser 49.5x12.5x11.7)	18

COMPLIES WITH:

REGULATION (EU) No 528/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 May 2012 concerning the making available on the market and use of biocidal products.

EN 13624 Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area - Test method and requirements (phase 2, step 1)

EN 13727 Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity in the medical area - Test method and requirements (phase 2, step 1)

EN 12791 Chemical disinfectants and antiseptics - Surgical hand disinfection - Test method and requirements (phase 2, step 2)

ISO 9001 certified company.

Nº REG. AEMPS: 833-DES

