



## TECHNICAL DATA SHEET - Medical device

<b>1. Administrative information about the company</b>											
1.1	<b>Company name:</b> CADENCE										
1.2	<b>Complete address:</b> 2 bis, Chemin du Loup 93290 TREMBLAY-EN-FRANCE										
1.3	<b>Material safety contact details:</b> Claudia Régnier	Tel: <a href="tel:+33145913182">+33145913182</a> Email : <a href="mailto:claudia.regnier.qual@gacd.fr">claudia.regnier.qual@gacd.fr</a>									
<b>2. Information on the device or equipment</b>											
2.1	<b>Common name:</b> DENTO-VIRACTIS 56										
2.2	<b>Commercial name:</b> DENTO-VIRACTIS 56 INSTRUPOWDER										
2.3	<b>GMDN nomenclature code:</b> 47631 <b>EMDN code</b> (or Cladimed for transitional phase): D99										
2.4	<b>LPP code</b> (List of Products and Services): N/A										
2.5	<b>DM class:</b> IIb Notified body number: GMED CE0459 Date first placed on the market in the EU: 2021-05  <b>DM manufacturer :</b> FRANK LAB 3 avenue des Frênes, ZA de l'Observatoire 78180 MONTIGNY-LE-BRETONNEUX FRANCE										
2.6	<b>Description of the device :</b>  Powdered enzymatic detergent-disinfectant for the pre-disinfection of medical devices.										
2.7	<b>Conditioning / packaging :</b>										
	<table border="1"> <thead> <tr> <th>PRODUCT ITEM</th> <th>PRODUCT DESCRIPTION</th> <th>SALES UNITS</th> </tr> </thead> <tbody> <tr> <td>3160881</td> <td>DENTO-VIRACTIS 56 INSTRUPOWDER (2 KG)</td> <td>2 KG bucket</td> </tr> <tr> <td>3160882</td> <td>DENTO-VIRACTIS 56 INSTRUPOWDER (4 KG)</td> <td>4 KG bucket</td> </tr> </tbody> </table>		PRODUCT ITEM	PRODUCT DESCRIPTION	SALES UNITS	3160881	DENTO-VIRACTIS 56 INSTRUPOWDER (2 KG)	2 KG bucket	3160882	DENTO-VIRACTIS 56 INSTRUPOWDER (4 KG)	4 KG bucket
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# DENTO-VIRACTIS INSTRUPOWDER 56



2.8	<b>Device composition and accessories :</b>  <table border="1" style="width: 100%; text-align: center;"> <tr style="background-color: #ff0066; color: white;"> <th colspan="3">Presence of :</th> </tr> <tr> <th colspan="3">YES / NO</th> </tr> <tr> <td style="width: 50%;">Latex</td> <td style="width: 25%;"><input type="checkbox"/> YES</td> <td style="width: 25%;"><input checked="" type="checkbox"/> NO</td> </tr> <tr> <td>Phtalates (DHP)</td> <td><input type="checkbox"/> YES</td> <td><input checked="" type="checkbox"/> NO</td> </tr> <tr> <td>Products of animal or organic origin</td> <td><input checked="" type="checkbox"/> YES</td> <td><input type="checkbox"/> NO</td> </tr> <tr> <td>Carcinogenic substances</td> <td><input type="checkbox"/> YES</td> <td><input checked="" type="checkbox"/> NO</td> </tr> <tr> <td>Endocrine disruptors</td> <td><input type="checkbox"/> YES</td> <td><input checked="" type="checkbox"/> NO</td> </tr> </table>	Presence of :			YES / NO			Latex	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO	Phtalates (DHP)	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO	Products of animal or organic origin	<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO	Carcinogenic substances	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO	Endocrine disruptors	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO
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<b>3. Sterilisation process:</b>																						
	Sterile medical devices : NO Device sterilisation method :N/A Single-use DM: NO																					
<b>4. Conservation and storage conditions</b>																						
	Normal storage conditions, Store in a dry environment at temperatures between 5 and 35° C. Special precautions: Store in a dry place away from moisture and heat. Presence of temperature indicators: YES																					
<b>5. Directions for use</b>																						
	Refer to the leaflet for further information on instructions for use, indications, precautions for use and contraindications.																					