



# NSAI

## Quality System Approval Certificate Medical Devices Directive 93/42/EEC

*The National Standards Authority of Ireland as a duly designated  
Notified Body, (identification number 0050), for the purposes of the European Communities  
(Medical Devices) Regulations (S.I. No. 252 of 1994)*

**APPROVES THE QUALITY SYSTEM APPLIED BY**

### Medentech

**Clonard Road  
Wexford  
Ireland**

*to the Product Family*

### Klorkleen Medical

**GMDN Code: 47631**

*on the basis of examination under the requirements of Directive 93/42/EEC on Medical Devices, Annex  
II, excluding (4)*

*The use of the NSAI Notified Body identification number 0050 in conjunction with CE Marking of  
Conformance for this product family is hereby authorised.*

<b>Registration Number:</b>	<b>252.1237</b>
<b>Original Approval:</b>	<b>05 May 2021</b>
<b>Last Amended on:</b>	<b>05 May 2021</b>
<b>Remains valid until:</b>	<b>26 May 2024</b>

**Signed:**

Approved by:  
Dr. Caroline Dore Geraghty  
Director, Medical Devices

Approved by:  
Dr. Elaine Darcy  
European Medical Device Operations Manager

**This certificate remains valid on condition that the Approved Quality System is maintained in an adequate and efficacious manner.**

Details of the operational locations included within the scope of this approval can be obtained from NSAI

In the case of a Class III device, this certificate must be supported by a valid design examination certificate

**National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland.**