

We, Mölnlycke Health Care AB, Gamlestadsvägen 3C, Box 13080, SE-402 52 Göteborg, Sweden being exclusively responsible manufacturer for conformity of the device/s; declare that the devices listed in the attached schedule are in conformity with the provisions of the Council Directive 93/42/EEC of 14 June 1993, as amended by 2007/47/EEC, concerning medical devices, the Medical Devices Act SFS 1993:584 and the Swedish Medical Product Agency regulations and guidelines: Medical Devices, LVFS 2003:11, as amended by LVFS 2009:18.

Trade name/ Product name:	<b>Biogel Synthetic Sterile Surgical Gloves</b>
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Product classification: **IIa**Sterility Status: **Sterile**Measuring function: **No**

This declaration is supported by a conformity assessment procedure in accordance with	
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Annex/es:	<b>II</b>
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Certificate number:	<b>CE 01965</b>
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Issued by:	<b>BSI (2797)</b>
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For non sterile, non-measuring Class I products, no certificate is issued by a Notified Body.	
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Mölnlycke Health Care issues this declaration in recognition of all applicable harmonised standards.

Signed for and on behalf of Mölnlycke Health Care

Date: **2019-10-23**Function: **Regulatory Affairs Manager  
(Antiseptics)**Name: **Victoria Stead**

Signature:



**Product(s) covered by this declaration:**

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
28855	Biogel Skinsense Indicator 5.5 x 2x25	57970 Polychloroprene surgical glove, non-powdered
28860	Biogel Skinsense Indicator 6.0 x 2x25	57970 Polychloroprene surgical glove, non-powdered
28865	Biogel Skinsense Indicator 6.5 x 2x25	57970 Polychloroprene surgical glove, non-powdered
28870	Biogel Skinsense Indicator 7.0 x 2x25	57970 Polychloroprene surgical glove, non-powdered
28875	Biogel Skinsense Indicator 7.5 x 2x25	57970 Polychloroprene surgical glove, non-powdered
28880	Biogel Skinsense Indicator 8.0 x 2x25	57970 Polychloroprene surgical glove, non-powdered
28885	Biogel Skinsense Indicator 8.5 x 2x25	57970 Polychloroprene surgical glove, non-powdered
31455	Biogel Skinsense 5.5x50	57970 Polychloroprene surgical glove, non-powdered

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
31460	Biogel Skinsense 6.0x50	57970 Polychloroprene surgical glove, non-powdered
31465	Biogel Skinsense 6.5x50	57970 Polychloroprene surgical glove, non-powdered
31470	Biogel Skinsense 7.0x50	57970 Polychloroprene surgical glove, non-powdered
31475	Biogel Skinsense 7.5x50	57970 Polychloroprene surgical glove, non-powdered
31480	Biogel Skinsense 8.0x50	57970 Polychloroprene surgical glove, non-powdered
31485	Biogel Skinsense 8.5x50	57970 Polychloroprene surgical glove, non-powdered
40655	Biogel Skinsense Underglove 5.5x50	57970 Polychloroprene surgical glove, non-powdered
40660	Biogel Skinsense Underglove 6.0x50	57970 Polychloroprene surgical glove, non-powdered
40665	Biogel Skinsense Underglove 6.5x50	57970 Polychloroprene surgical glove, non-powdered

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
40670	Biogel Skinsense Underglove 7.0x50	57970 Polychloroprene surgical glove, non-powdered
40675	Biogel Skinsense Underglove 7.5x50	57970 Polychloroprene surgical glove, non-powdered
40680	Biogel Skinsense Underglove 8.0x50	57970 Polychloroprene surgical glove, non-powdered
40685	Biogel Skinsense Underglove 8.5x50	57970 Polychloroprene surgical glove, non-powdered
40690	Biogel Skinsense Underglove 9.0x40	57970 Polychloroprene surgical glove, non-powdered
40855	Biogel Skinsense PI 5.5 x50	56293 Polyisoprene surgical glove, non-powdered
40860	Biogel Skinsense PI 6.0 x50	56293 Polyisoprene surgical glove, non-powdered
40865	Biogel Skinsense PI 6.5 x50	56293 Polyisoprene surgical glove, non-powdered
40870	Biogel Skinsense PI 7.0 x50	56293 Polyisoprene surgical glove, non-powdered
40875	Biogel Skinsense PI 7.5 x50	56293 Polyisoprene surgical glove, non-powdered

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
40880	Biogel Skinsense PI 8.0 x50	56293 Polyisoprene surgical glove, non-powdered
40955	Biogel PI UltraTouch 5.5x50	56293 Polyisoprene surgical glove, non-powdered
40960	Biogel PI UltraTouch 6.0x50	56293 Polyisoprene surgical glove, non-powdered
40965	Biogel PI UltraTouch 6.5x50	56293 Polyisoprene surgical glove, non-powdered
40970	Biogel PI UltraTouch 7.0x50	56293 Polyisoprene surgical glove, non-powdered
40975	Biogel PI UltraTouch 7.5x50	56293 Polyisoprene surgical glove, non-powdered
40980	Biogel PI UltraTouch 8.0x50	56293 Polyisoprene surgical glove, non-powdered
40985	Biogel PI UltraTouch 8.5x50	56293 Polyisoprene surgical glove, non-powdered
40990	Biogel PI UltraTouch 9.0x40	56293 Polyisoprene surgical glove, non-powdered
41155	Biogel PI UltraTouch 5.5 x50	56293 Polyisoprene surgical glove, non-powdered
41160	Biogel PI UltraTouch 6.0 x50	56293 Polyisoprene surgical glove, non-powdered

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
41165	Biogel PI UltraTouch 6.5 x50	56293 Polyisoprene surgical glove, non-powdered
41170	Biogel PI UltraTouch 7.0 x50	56293 Polyisoprene surgical glove, non-powdered
41175	Biogel PI UltraTouch 7.5 x50	56293 Polyisoprene surgical glove, non-powdered
41180	Biogel PI UltraTouch 8.0 x50	56293 Polyisoprene surgical glove, non-powdered
41185	Biogel PI UltraTouch 8.5 x50	56293 Polyisoprene surgical glove, non-powdered
41190	Biogel PI UltraTouch 9.0 x40	56293 Polyisoprene surgical glove, non-powdered
41455	Biogel PI Indicator System 5.5 2 x 25	56293 Polyisoprene surgical glove, non-powdered
41460	Biogel PI Indicator System 6.0 2 x 25	56293 Polyisoprene surgical glove, non-powdered
41465	Biogel PI Indicator System 6.5 2 x 25	56293 Polyisoprene surgical glove, non-powdered
41470	Biogel PI Indicator System 7.0 2 x 25	56293 Polyisoprene surgical glove, non-powdered
41475	Biogel PI Indicator System 7.5 2 x 25	56293 Polyisoprene surgical glove, non-powdered

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
41480	Biogel PI Indicator System 8.0 2 x 25	56293 Polyisoprene surgical glove, non-powdered
41485	Biogel PI Indicator System 8.5 2 x 25	56293 Polyisoprene surgical glove, non-powdered
41655	Biogel PI Indicator Underglove 5.5 x 50	56293 Polyisoprene surgical glove, non-powdered
41660	Biogel PI Indicator Underglove 6.0 x 50	56293 Polyisoprene surgical glove, non-powdered
41665	Biogel PI Indicator Underglove 6.5 x 50	56293 Polyisoprene surgical glove, non-powdered
41670	Biogel PI Indicator Underglove 7.0 x 50	56293 Polyisoprene surgical glove, non-powdered
41675	Biogel PI Indicator Underglove 7.5 x 50	56293 Polyisoprene surgical glove, non-powdered
41680	Biogel PI Indicator Underglove 8.0 x 50	56293 Polyisoprene surgical glove, non-powdered
41685	Biogel PI Indicator Underglove 8.5 x 50	56293 Polyisoprene surgical glove, non-powdered
41690	Biogel PI Indicator Underglove 9.0 x 40	56293 Polyisoprene surgical glove, non-powdered
42155	Biogel PI UltraTouch G 5.5x50	56293 Polyisoprene surgical glove, non-powdered

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
42160	Biogel PI UltraTouch G 6.0x50	56293 Polyisoprene surgical glove, non-powdered
42165	Biogel PI UltraTouch G 6.5x50	56293 Polyisoprene surgical glove, non-powdered
42170	Biogel PI UltraTouch G 7.0x50	56293 Polyisoprene surgical glove, non-powdered
42175	Biogel PI UltraTouch G 7.5x50	56293 Polyisoprene surgical glove, non-powdered
42180	Biogel PI UltraTouch G 8.0x50	56293 Polyisoprene surgical glove, non-powdered
42185	Biogel PI UltraTouch G 8.5x50	56293 Polyisoprene surgical glove, non-powdered
42190	Biogel PI UltraTouch G 9.0x40	56293 Polyisoprene surgical glove, non-powdered
42655	Biogel PI UltraTouch M 5.5x50	56293 Polyisoprene surgical glove, non-powdered
42660	Biogel PI UltraTouch M 6.0x50	56293 Polyisoprene surgical glove, non-powdered
42665	Biogel PI UltraTouch M 6.5x50	56293 Polyisoprene surgical glove, non-powdered
42670	Biogel PI UltraTouch M 7.0x50	56293 Polyisoprene surgical glove, non-powdered



<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
42675	Biogel PI UltraTouch M 7.5x50	56293 Polyisoprene surgical glove, non-powdered
42680	Biogel PI UltraTouch M 8.0x50	56293 Polyisoprene surgical glove, non-powdered
42685	Biogel PI UltraTouch M 8.5x50	56293 Polyisoprene surgical glove, non-powdered
42690	Biogel PI UltraTouch M 9.0x40	56293 Polyisoprene surgical glove, non-powdered
42955	Biogel NeoDerm 5.5x50	57970 Polychloroprene surgical glove, non-powdered
42960	Biogel NeoDerm 6.0x50	57970 Polychloroprene surgical glove, non-powdered
42965	Biogel NeoDerm 6.5x50	57970 Polychloroprene surgical glove, non-powdered
42970	Biogel NeoDerm 7.0x50	57970 Polychloroprene surgical glove, non-powdered
42975	Biogel NeoDerm 7.5x50	57970 Polychloroprene surgical glove, non-powdered
42980	Biogel NeoDerm 8.0x50	57970 Polychloroprene surgical glove, non-powdered

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
42985	Biogel NeoDerm 8.5x50	57970 Polychloroprene surgical glove, non- powdered
42990	Biogel NeoDerm 9.0x40	57970 Polychloroprene surgical glove, non- powdered
43155	Biogel PI UltraTouch 5.5x50	56293 Polyisoprene surgical glove, non- powdered
43160	Biogel PI UltraTouch 6.0x50	56293 Polyisoprene surgical glove, non- powdered
43165	Biogel PI UltraTouch 6.5x50	56293 Polyisoprene surgical glove, non- powdered
43170	Biogel PI UltraTouch 7.0x50	56293 Polyisoprene surgical glove, non- powdered
43175	Biogel PI UltraTouch 7.5x50	56293 Polyisoprene surgical glove, non- powdered
43180	Biogel PI UltraTouch 8.0x50	56293 Polyisoprene surgical glove, non- powdered
43185	Biogel PI UltraTouch 8.5x50	56293 Polyisoprene surgical glove, non- powdered
43190	Biogel PI UltraTouch 9.0x40	56293 Polyisoprene surgical glove, non- powdered
4440955	Biogel PI UltraTouch 5.5x50	56293 Polyisoprene surgical glove, non- powdered

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
4440960	Biogel PI UltraTouch 6.0x50	56293 Polyisoprene surgical glove, non-powdered
4440965	Biogel PI UltraTouch 6.5x50	56293 Polyisoprene surgical glove, non-powdered
4440970	Biogel PI UltraTouch 7.0x50	56293 Polyisoprene surgical glove, non-powdered
4440975	Biogel PI UltraTouch 7.5x50	56293 Polyisoprene surgical glove, non-powdered
4440980	Biogel PI UltraTouch 8.5x50	56293 Polyisoprene surgical glove, non-powdered
4440985	Biogel PI UltraTouch 8.0x50	56293 Polyisoprene surgical glove, non-powdered
4440990	Biogel PI UltraTouch 9.0x40	56293 Polyisoprene surgical glove, non-powdered
4441655	Biogel PI Indicator Underglove 5.5x50	56293 Polyisoprene surgical glove, non-powdered
4441660	Biogel PI Indicator Underglove 6.0 x 50	56293 Polyisoprene surgical glove, non-powdered
4441665	Biogel PI Indicator Underglove 6.5 x 50	56293 Polyisoprene surgical glove, non-powdered
4441670	Biogel PI Indicator Underglove 7.0 x 50	56293 Polyisoprene surgical glove, non-powdered

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
4441675	Biogel PI Indicator Underglove 7.5 x 50	56293 Polyisoprene surgical glove, non-powdered
4441680	Biogel PI Indicator Underglove 8.0 x 50	56293 Polyisoprene surgical glove, non-powdered
4441685	Biogel PI Indicator Underglove 8.5 x 50	56293 Polyisoprene surgical glove, non-powdered
4441690	Biogel PI Indicator Underglove 9.0 x 40	56293 Polyisoprene surgical glove, non-powdered
4443155	Biogel PI UltraTouch 5.5x50	56293 Polyisoprene surgical glove, non-powdered
4443160	Biogel PI UltraTouch 6.0x50	56293 Polyisoprene surgical glove, non-powdered
4443165	Biogel PI UltraTouch 6.5x50	56293 Polyisoprene surgical glove, non-powdered
4443170	Biogel PI UltraTouch 7.0x50	56293 Polyisoprene surgical glove, non-powdered
4443175	Biogel PI UltraTouch 7.5x50	56293 Polyisoprene surgical glove, non-powdered
4443180	Biogel PI UltraTouch 8.0x50	56293 Polyisoprene surgical glove, non-powdered
4443185	Biogel PI UltraTouch 8.5x50	56293 Polyisoprene surgical glove, non-powdered

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
4443190	Biogel PI UltraTouch 9.0x50	56293 Polyisoprene surgical glove, non-powdered
4450955	Biogel NeoTech 5.5 x 50	57970 Polychloroprene surgical glove, non-powdered
4450960	Biogel NeoTech 6.0 x 50	57970 Polychloroprene surgical glove, non-powdered
4450965	Biogel NeoTech 6.5 x 50	57970 Polychloroprene surgical glove, non-powdered
4450970	Biogel NeoTech 7.0 x 50	57970 Polychloroprene surgical glove, non-powdered
4450975	Biogel NeoTech 7.5 x 50	57970 Polychloroprene surgical glove, non-powdered
4450980	Biogel NeoTech 8.0 x 50	57970 Polychloroprene surgical glove, non-powdered
4450985	Biogel NeoTech 8.5 x 50	57970 Polychloroprene surgical glove, non-powdered
4450990	Biogel NeoTech 9.0 x 40	57970 Polychloroprene surgical glove, non-powdered

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
45355	Biogel PI UltraTouch S Indicator System 5.5x50	56293 Polyisoprene surgical glove, non-powdered
45360	Biogel PI UltraTouch S Indicator System 6.0x50	56293 Polyisoprene surgical glove, non-powdered
45365	Biogel PI UltraTouch S Indicator System 6.5x50	56293 Polyisoprene surgical glove, non-powdered
45370	Biogel PI UltraTouch S Indicator System 7.0x50	56293 Polyisoprene surgical glove, non-powdered
45375	Biogel PI UltraTouch S Indicator System 7.5x50	56293 Polyisoprene surgical glove, non-powdered
45380	Biogel PI UltraTouch S Indicator System 8.0x50	56293 Polyisoprene surgical glove, non-powdered
45385	Biogel PI UltraTouch S Indicator System 8.5x50	56293 Polyisoprene surgical glove, non-powdered
45555	Biogel PI UltraTouch S 5.5x50	56293 Polyisoprene surgical glove, non-powdered
45560	Biogel PI UltraTouch S 6.0x50	56293 Polyisoprene surgical glove, non-powdered
45565	Biogel PI UltraTouch S 6.5x50	56293 Polyisoprene surgical glove, non-powdered
45570	Biogel PI UltraTouch S 7.0x50	56293 Polyisoprene surgical glove, non-powdered

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
45575	Biogel PI UltraTouch S 7.5x50	56293 Polyisoprene surgical glove, non-powdered
45580	Biogel PI UltraTouch S 8.0x50	56293 Polyisoprene surgical glove, non-powdered
45585	Biogel PI UltraTouch S 8.5x50	56293 Polyisoprene surgical glove, non-powdered
45590	Biogel PI UltraTouch S 9.0x40	56293 Polyisoprene surgical glove, non-powdered
45955	Biogel PI UltraTouch S Indicator Underglove 5.5x50	56293 Polyisoprene surgical glove, non-powdered
45960	Biogel PI UltraTouch S Indicator Underglove 6.0x50	56293 Polyisoprene surgical glove, non-powdered
45965	Biogel PI UltraTouch S Indicator Underglove 6.5x50	56293 Polyisoprene surgical glove, non-powdered
45970	Biogel PI UltraTouch S Indicator Underglove 7.0x50	56293 Polyisoprene surgical glove, non-powdered
45975	Biogel PI UltraTouch S Indicator Underglove 7.5x50	56293 Polyisoprene surgical glove, non-powdered
45980	Biogel PI UltraTouch S Indicator Underglove 8.0x50	56293 Polyisoprene surgical glove, non-powdered
45985	Biogel PI UltraTouch S Indicator Underglove 8.5x50	56293 Polyisoprene surgical glove, non-powdered

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
45990	Biogel PI UltraTouch S Indicator Underglove 9.0x40	56293 Polyisoprene surgical glove, non-powdered
47660	Biogel PI OrthoPro 6.0x40	56293 Polyisoprene surgical glove, non-powdered
47665	Biogel PI OrthoPro 6.5x40	56293 Polyisoprene surgical glove, non-powdered
47670	Biogel PI OrthoPro 7.0x40	56293 Polyisoprene surgical glove, non-powdered
47675	Biogel PI OrthoPro 7.5x40	56293 Polyisoprene surgical glove, non-powdered
47680	Biogel PI OrthoPro 8.0x40	56293 Polyisoprene surgical glove, non-powdered
47685	Biogel PI OrthoPro 8.5x40	56293 Polyisoprene surgical glove, non-powdered
47690	Biogel PI OrthoPro 9.0x40	56293 Polyisoprene surgical glove, non-powdered
47960	Biogel PI Pro-Fit 6.0x50	56293 Polyisoprene surgical glove, non-powdered
47965	Biogel PI Pro-Fit 6.5x50	56293 Polyisoprene surgical glove, non-powdered
47970	Biogel PI Pro-Fit 7.0x50	56293 Polyisoprene surgical glove, non-powdered



<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
47975	Biogel PI Pro-Fit 7.5x50	56293 Polyisoprene surgical glove, non-powdered
47980	Biogel PI Pro-Fit 8.0x50	56293 Polyisoprene surgical glove, non-powdered
47985	Biogel PI Pro-Fit 8.5x50	56293 Polyisoprene surgical glove, non-powdered
47990	Biogel PI Pro-Fit 9.0x40	56293 Polyisoprene surgical glove, non-powdered
48355	Biogel PI Micro Indicator System 5.5x50	56293 Polyisoprene surgical glove, non-powdered
48360	Biogel PI Micro Indicator System 6.0x50	56293 Polyisoprene surgical glove, non-powdered
48365	Biogel PI Micro Indicator System 6.5x50	56293 Polyisoprene surgical glove, non-powdered
48370	Biogel PI Micro Indicator System 7.0x50	56293 Polyisoprene surgical glove, non-powdered
48375	Biogel PI Micro Indicator System 7.5x50	56293 Polyisoprene surgical glove, non-powdered
48380	Biogel PI Micro Indicator System 8.0x50	56293 Polyisoprene surgical glove, non-powdered
48385	Biogel PI Micro Indicator System 8.5x50	56293 Polyisoprene surgical glove, non-powdered

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
48555	Biogel PI Micro 5.5x50	56293 Polyisoprene surgical glove, non-powdered
48560	Biogel PI Micro 6.0x50	56293 Polyisoprene surgical glove, non-powdered
48565	Biogel PI Micro 6.5x50	56293 Polyisoprene surgical glove, non-powdered
48570	Biogel PI Micro 7.0x50	56293 Polyisoprene surgical glove, non-powdered
48575	Biogel PI Micro 7.5x50	56293 Polyisoprene surgical glove, non-powdered
48580	Biogel PI Micro 8.0x50	56293 Polyisoprene surgical glove, non-powdered
48585	Biogel PI Micro 8.5x50	56293 Polyisoprene surgical glove, non-powdered
48590	Biogel PI Micro 9.0x50	56293 Polyisoprene surgical glove, non-powdered
48955	Biogel PI Micro Indicator Underglove 5.5x50	56293 Polyisoprene surgical glove, non-powdered
48960	Biogel PI Micro Indicator Underglove 6.0x50	56293 Polyisoprene surgical glove, non-powdered
48965	Biogel PI Micro Indicator Underglove 6.5x50	56293 Polyisoprene surgical glove, non-powdered

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
48970	Biogel PI Micro Indicator Underglove 7.0x50	56293 Polyisoprene surgical glove, non- powdered
48975	Biogel PI Micro Indicator Underglove 7.5x50	56293 Polyisoprene surgical glove, non- powdered
48980	Biogel PI Micro Indicator Underglove 8.0x50	56293 Polyisoprene surgical glove, non- powdered
48985	Biogel PI Micro Indicator Underglove 8.5x50	56293 Polyisoprene surgical glove, non- powdered
48990	Biogel PI Micro Indicator Underglove 9.0x40	56293 Polyisoprene surgical glove, non- powdered
50955	Biogel Skinsense 5.5x50	57970 Polychloroprene surgical glove, non- powdered
50960	Biogel Skinsense 6.0x50	57970 Polychloroprene surgical glove, non- powdered
50965	Biogel Skinsense 6.5x50	57970 Polychloroprene surgical glove, non- powdered
50970	Biogel Skinsense 7.0x50	57970 Polychloroprene surgical glove, non- powdered
50975	Biogel Skinsense 7.5x50	57970 Polychloroprene surgical glove, non- powdered

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
50980	Biogel Skinsense 8.0x50	57970 Polychloroprene surgical glove, non- powdered
50985	Biogel Skinsense 8.5x50	57970 Polychloroprene surgical glove, non- powdered
50990	Biogel Skinsense 9.0x40	57970 Polychloroprene surgical glove, non- powdered