

EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex II Section 4

No.

CE 727385

Issued To:

**Mentor Medical Systems B.V.
Zernikedreef 2
Leiden
2333 CL
The Netherlands**

In respect of:

MENTOR® Round Gel Breast Implants Cohesive I and Cohesive II

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2021-02-08**

Date: **2021-02-08**

Expiry Date: **2024-05-26**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

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Catalogue Number	Device Name	Model, Type	Intended Purpose per IFU	Classification
354-1007 354-1257 354-1507 354-1757 354-2007 354-2257 354-2507 354-2757 354-3007 354-3257 354-3507 354-3757 354-4007 354-4507 354-5007 354-5507 354-6007 354-7007 354-8007	SILTEX® Round Moderate Profile Gel Breast Implants Cohesive I™	100cc 125cc 150cc 175cc 200cc 225cc 250cc 275cc 300cc 325cc 350cc 375cc 400cc 450cc 500cc 550cc 600cc 700cc 800cc	The Mentor Breast Implants intended purpose is to replace missing breast tissue or to enhance a breast in females undergoing breast augmentation or breast reconstruction.	III

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Catalogue Number	Device Name	Model, Type	Intended Purpose per IFU	Classification
354-1009	SILTEX® Round Moderate Profile Gel Breast Implants Cohesive II™	100cc	The Mentor Breast Implants intended purpose is to replace missing breast tissue or to enhance a breast in females undergoing breast augmentation or breast reconstruction.	III
354-1259				
354-1509				
354-1759				
354-2009				
354-2259				
354-2509				
354-2759				
354-3009				
354-3259				
354-3509				
354-3759				
354-4009				
354-4509				
354-5009				
354-5509				
354-6009				
354-7009				
354-8009				

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Catalogue Number	Device Name	Model, Type	Intended Purpose per IFU	Classification
354-1001 354-1251 354-1501 354-1751 354-2001 354-2251 354-2501 354-2751 354-3001 354-3251 354-3501 354-3751 354-4001 354-4501 354-5001 354-5501 354-6001 354-7001 354-8001	SILTEX™ Round Moderate Plus Profile Gel Breast Implants Cohesive I™	100cc 125cc 150cc 175cc 200cc 225cc 250cc 275cc 300cc 325cc 350cc 375cc 400cc 450cc 500cc 550cc 600cc 700cc 800cc	The Mentor Breast Implants intended purpose is to replace missing breast tissue or to enhance a breast in females undergoing breast augmentation or breast reconstruction.	III

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Catalogue Number	Device Name	Model, Type	Intended Purpose per IFU	Classification
324-5125 324-5150 324-5175 324-5200 324-5225 324-5250 324-5275 324-5300 324-5325 324-5350 324-5375 324-5400 324-5450 324-5500 324-5550 324-5600 324-5700 324-5800	SILTEX™ Round Moderate Plus Profile Gel Breast Implant Cohesive II™	125cc 150cc 175cc 200cc 225cc 250cc 275cc 300cc 325cc 350cc 375cc 400cc 450cc 500cc 550cc 600cc 700cc 800cc	The Mentor Breast Implants intended purpose is to replace missing breast tissue or to enhance a breast in females undergoing breast augmentation or breast reconstruction.	III

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Catalogue Number	Device Name	Model, Type	Intended Purpose per IFU	Classification
354-4125	SILTEX™ Round High Profile Gel Breast Implants Cohesive I™	125cc	The Mentor Breast Implants intended purpose is to replace missing breast tissue or to enhance a breast in females undergoing breast augmentation or breast reconstruction.	III
354-4150				
354-4175				
354-4200				
354-4225				
354-4250				
354-4275				
354-4300				
354-4325				
354-4350				
354-4375				
354-4400				
354-4425				
354-4450				
354-4500				
354-4550				
354-4600				
354-4650				
354-4700				
354-4800				

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324-4125	SILTEX™ Round High Profile Gel Breast Implants Cohesive II™	125cc	The Mentor Breast Implants intended purpose is to replace missing breast tissue or to enhance a breast in females undergoing breast augmentation or breast reconstruction.	III
324-4150				
324-4175				
324-4200				
324-4225				
324-4250				
324-4275				
324-4300				
324-4325				
324-4350				
324-4375				
324-4400				
324-4425				
324-4450				
324-4500				
324-4550				
324-4600				
324-4650				
324-4700				
324-4800				

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Catalogue Number	Device Name	Model, Type	Intended Purpose per IFU	Classification
354-5135	SILTEX™ Round Ultra High Profile Gel Breast Implants Cohesive I™	135cc	The Mentor Breast Implants intended purpose is to replace missing breast tissue or to enhance a breast in females undergoing breast augmentation or breast reconstruction.	III
354-5160		160cc		
354-5185		185cc		
354-5215		215cc		
354-5240		240cc		
354-5270		270cc		
354-5295		295cc		
354-5320		320cc		
354-5350		350cc		
354-5375		375cc		
354-5400		400cc		
354-5430		430cc		
354-5455		455cc		
354-5480		480cc		
354-5535		535cc		
354-5590	590cc			

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Catalogue Number	Device Name	Model, Type	Intended Purpose per IFU	Classification
350-7125BC	Smooth Round Moderate Profile Gel Breast Implants Cohesive I™	125cc	The Mentor Breast Implants intended purpose is to replace missing breast tissue or to enhance a breast in females undergoing breast augmentation or breast reconstruction.	III
350-7150BC				
350-7175BC				
350-7200BC				
350-7225BC				
350-7250BC				
350-7275BC				
350-7300BC				
350-7325BC				
350-7350BC				
350-7375BC				
350-7400BC				
350-7450BC				
350-7500BC				
350-7550BC				
350-7600BC				
350-7700BC				
350-7800BC				

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Catalogue Number	Device Name	Model, Type	Intended Purpose per IFU	Classification
350-1251BC 350-1501BC 350-1751BC 350-2001BC 350-2251BC 350-2501BC 350-2751BC 350-3001BC 350-3251BC 350-3501BC 350-3751BC 350-4001BC 350-4501BC 350-5001BC 350-5501BC 350-6001BC 350-7001BC 350-8001BC	Smooth Round Moderate Plus Profile Gel Breast Implants Cohesive I™	125cc 150cc 175cc 200cc 225cc 250cc 275cc 300cc 325cc 350cc 375cc 400cc 450cc 500cc 550cc 600cc 700cc 800cc	The Mentor Breast Implants intended purpose is to replace missing breast tissue or to enhance a breast in females undergoing breast augmentation or breast reconstruction.	III

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Catalogue Number	Device Name	Model, Type	Intended Purpose per IFU	Classification
350-1254BC	Smooth Round High Profile Gel Breast Implants Cohesive I™	125cc	The Mentor Breast Implants intended purpose is to replace missing breast tissue or to enhance a breast in females undergoing breast augmentation or breast reconstruction.	III
350-1504BC				
350-1754BC				
350-2004BC				
350-2254BC				
350-2504BC				
350-2754BC				
350-3004BC				
350-3254BC				
350-3504BC				
350-3754BC				
350-4004BC				
350-4254BC				
350-4504BC				
350-5004BC				
350-5504BC				
350-6004BC				
350-6504BC				
350-7004BC				
350-8004BC				

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Catalogue Number	Device Name	Model, Type	Intended Purpose per IFU	Classification
350-5135BC 350-5160BC 350-5185BC 350-5215BC 350-5240BC 350-5270BC 350-5295BC 350-5320BC 350-5350BC 350-5375BC 350-5400BC 350-5430BC 350-5455BC 350-5480BC 350-5535BC 350-5590BC	Smooth Round Ultra High Profile Gel Breast Implants Cohesive I™	135cc 160cc 185cc 215cc 240cc 270cc 295cc 320cc 350cc 375cc 400cc 430cc 455cc 480cc 535cc 590cc	The Mentor Breast Implants intended purpose is to replace missing breast tissue or to enhance a breast in females undergoing breast augmentation or breast reconstruction.	III

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Catalogue Number	Device Name	Model, Type	Intended Purpose per IFU	Classification
SMPX-130	Smooth Round Moderate Plus Profile Xtra Gel Breast Implants	130cc	The Mentor Breast Implants intended purpose is to replace missing breast tissue or to enhance a breast in females undergoing breast augmentation or breast reconstruction.	III
SMPX-160		160cc		
SMPX-190		190cc		
SMPX-215		215cc		
SMPX-240		240cc		
SMPX-270		270cc		
SMPX-295		295cc		
SMPX-325		325cc		
SMPX-350		350cc		
SMPX-370		370cc		
SMPX-405		405cc		
SMPX-440		440cc		
SMPX-490		490cc		
SMPX-545		545cc		
SMPX-605		605cc		
SMPX-645		645cc		
SMPX-755		755cc		
SMPX130C		130cc		
SMPX160C		160cc		
SMPX190C		190cc		
SMPX215C		215cc		
SMPX240C		240cc		
SMPX270C		270cc		
SMPX295C		295cc		
SMPX325C		325cc		
SMPX350C		350cc		

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Catalogue Number	Device Name	Model, Type	Intended Purpose per IFU	Classification
SMPX370C SMPX405C SMPX440C SMPX490C SMPX545C SMPX605C SMPX645C SMPX755C	Smooth Round Moderate Plus Profile Xtra Gel Breast Implants	370cc 405cc 440cc 490cc 545cc 605cc 645cc 755cc	The Mentor Breast Implants intended purpose is to replace missing breast tissue or to enhance a breast in females undergoing breast augmentation or breast reconstruction.	III
TMPX-130 TMPX-160 TMPX-190 TMPX-215 TMPX-240 TMPX-270 TMPX-295 TMPX-325 TMPX-350 TMPX-370 TMPX-405 TMPX-440 TMPX-490 TMPX-545 TMPX-605 TMPX-645 TMPX-755	SILTEX™ Round Moderate Plus Profile Xtra Gel Breast Implants	130cc 160cc 190cc 215cc 240cc 270cc 295cc 325cc 350cc 370cc 405cc 440cc 490cc 545cc 605cc 645cc 755cc	The Mentor Breast Implants intended purpose is to replace missing breast tissue or to enhance a breast in females undergoing breast augmentation or breast reconstruction.	III

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TMPX130C TMPX160C TMPX190C TMPX215C TMPX240C TMPX270C TMPX295C TMPX325C TMPX350C TMPX370C TMPX405C TMPX440C TMPX490C, TMPX545C TMPX605C TMPX645C TMPX755C	SILTEX™ Round Moderate Plus Profile Xtra Gel Breast Implants	130cc 160cc 190cc 215cc 240cc 270cc 295cc 325cc 350cc 370cc 405cc 440cc 490cc 545cc 605cc 645cc 755cc	The Mentor Breast Implants intended purpose is to replace missing breast tissue or to enhance a breast in females undergoing breast augmentation or breast reconstruction.	III
SHPX-150 SHPX-180 SHPX-200 SHPX-235 SHPX-260 SHPX-285 SHPX-335 SHPX-355	Smooth Round High Profile Xtra Gel Breast Implants	150cc 180cc 200cc 235cc 260cc 285cc 335cc 355cc		III

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SHPX-380	Smooth Round High Profile Xtra Gel Breast Implants	380cc	The Mentor Breast Implants intended purpose is to replace missing breast tissue or to enhance a breast in females undergoing breast augmentation or breast reconstruction.	III
SHPX-415		415cc		
SHPX-450		450cc		
SHPX-465		465cc		
SHPX-490		490cc		
SHPX-535		535cc		
SHPX-595		595cc		
SHPX-650		650cc		
SHPX-700		700cc		
SHPX-755		755cc		
SHPX-790		790cc		
SHPX150C		150cc		
SHPX180C		180cc		
SHPX200C		200cc		
SHPX235C		235cc		
SHPX260C		260cc		
SHPX285C		285cc		
SHPX335C		335cc		
SHPX355C		355cc		
SHPX380C		380cc		
SHPX415C	415cc			
SHPX450C	450cc			
SHPX465C	465cc			
SHPX490C	490cc			
SHPX535C	535cc			

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Catalogue Number	Device Name	Model, Type	Intended Purpose per IFU	Classification
SHPX595C SHPX650C SHPX700C SHPX755C SHPX790C	Smooth Round High Profile Xtra Gel Breast Implants	595cc 650cc 700cc 755cc 790cc	The Mentor Breast Implants intended purpose is to replace missing breast tissue or to enhance a breast in females undergoing breast augmentation or breast reconstruction.	III
THPX-150 THPX-175 THPX-200 THPX-230 THPX-255 THPX-285 THPX-325 THPX-340 THPX-365 THPX-405 THPX-425 THPX-455 THPX-470 THPX-515 THPX-570 THPX-620 THPX-680 THPX-725 THPX-765	SILTEX™ Round High Profile Xtra Gel Breast Implants	150cc 175cc 200cc 230cc 255cc 285cc 325cc 340cc 365cc 405cc 425cc 455cc 470cc 515cc 570cc 620cc 680cc 725cc 765cc		III

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Catalogue Number	Device Name	Model, Type	Intended Purpose per IFU	Classification
THPX150C THPX175C THPX200C THPX230C THPX255C THPX285C THPX325C THPX340C THPX365C THPX405C THPX425C THPX455C THPX470C THPX515C THPX570C THPX620C THPX680C THPX725C THPX765C	SILTEX™ Round High Profile Xtra Gel Breast Implants	150cc 175cc 200cc 230cc 255cc 285cc 325cc 340cc 365cc 405cc 425cc 455cc 470cc 515cc 570cc 620cc 680cc 725cc 765cc	The Mentor Breast Implants intended purpose is to replace missing breast tissue or to enhance a breast in females undergoing breast augmentation or breast reconstruction.	III

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Certificate History

Date	Reference Number	Action
Current	3170360	First issue. Transfer from another Notified Body and Renewal.

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