



## Konformitätserklärung *Declaration of Conformity*

Wir, die Firma

*We, the company*

THUASNE Deutschland GmbH  
Im Steinkamp 12, D-30938 Burgwedel  
Deutschland – *Germany*

**SRN** (Single Registration Number): DE-MF-000006210

erklären in alleiniger Verantwortung, dass unser/e Produkt/e in Anhang I, Anhang II und Anhang III

*declare under our sole responsibility, that our product/s in annex I, annex II and annex III*

den Anforderungen der Verordnung (EU) 2017/745 des Europäischen Parlaments und des Rates vom 05. April 2017 über Medizinprodukte entspricht/entsprechen.

*Complies with the requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.*

Unser Qualitätsmanagementsystem ist zertifiziert nach ISO 13485.

*Our quality management system is certified according to ISO 13485.*

<b>Klassifizierung</b>	<b>Klasse I</b> im Sinne von Anhang VIII der Verordnung (EU) 2017/745
<b>Classification</b>	<b>Class I</b> as defined in the Annex VIII of the Regulation (EU) 2017/745

Diese Erklärung gilt bis zum 06. Oktober 2023.


*This declaration is valid until October 6, 2023.*

Für THUASNE – *For THUASNE*

Burgwedel, 7. Juni 2021  
*Burgwedel, June 7, 2021*

DocuSigned by:  
  
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**Joachim Dehmel**  
Geschäftsführer  
*Managing Director*

DocuSigned by:  
  
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**Dr. Tjark Siedentop**  
Leiter Forschung & Entwicklung  
*Director Research & Development*



**Anhang I zur Konformitätserklärung**  
**vom 19.Mai 2021**  
**Appendix I of Declaration of Conformity**  
**of May 19<sup>th</sup> 2021**

<b>Produktcode</b> <i>Product code</i>	<b>Produkt- oder Handelsname</b> <i>Product name</i>	<b>Basis UDI-DI</b> <i>Basic UDI-DI</i>
20021B	VENOFLEX ELEGANCE SERIEAD KL2	4035459DE1402A3J
20023E	VENOFLEX ELEGANCE SERIEAG KL2	4035459DE1402A3J
20023H	VENOFLEX ELEGANCE SERIEAG+ KL2	4035459DE1402A3J
20025B	VENOFLEX ELEGANCE SERIEAT KL2	4035459DE1402A3J
20027B	VENOFLEX ELEGANCE SERIEAT/U KL2	4035459DE1402A3J
200214	VENOFLEX ELEGANCE MASSAD KL1	4035459DE1401A3F
200215	VENOFLEX ELEGANCE MASSAD KL2	4035459DE1401B3H
200216	VENOFLEX ELEGANCE MASSAD KL3	4035459DE1401C3K
200217	VENOFLEX ELEGANCE MASSAD KL1	4035459DE1401A3F
200218	VENOFLEX ELEGANCE MASSAD KL2	4035459DE1401B3H
200219	VENOFLEX ELEGANCE MASSAD KL3	4035459DE1401C3K
200224	VENOFLEX ELEGANCE MASSAF KL1	4035459DE1401A3F
200225	VENOFLEX ELEGANCE MASSAF KL2	4035459DE1401B3H
200226	VENOFLEX ELEGANCE MASSAF KL3	4035459DE1401C3K
200227	VENOFLEX ELEGANCE MASSAF KL1	4035459DE1401A3F
200228	VENOFLEX ELEGANCE MASSAF KL2	4035459DE1401B3H
200229	VENOFLEX ELEGANCE MASSAF KL3	4035459DE1401C3K
200234	VENOFLEX ELEGANCE MASSAG KL1	4035459DE1401A3F
200235	VENOFLEX ELEGANCE MASSAG KL2	4035459DE1401B3H
200236	VENOFLEX ELEGANCE MASSAG KL3	4035459DE1401C3K
200237	VENOFLEX ELEGANCE MASSAG KL1	4035459DE1401A3F



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200238	VENOFLEX ELEGANCE MASSAG KL2	4035459DE1401B3H
200239	VENOFLEX ELEGANCE MASSAG KL3	4035459DE1401C3K
200244	VENOFLEX ELEGANCE MASSAG/HAT KL1	4035459DE1401A3F
200245	VENOFLEX ELEGANCE MASSAG/HAT KL2	4035459DE1401B3H
200246	VENOFLEX ELEGANCE MASSAG/HAT KL3	4035459DE1401C3K
200254	VENOFLEX ELEGANCE MASSAT KL1	4035459DE1401A3F
200255	VENOFLEX ELEGANCE MASSAT KL2	4035459DE1401B3H
200256	VENOFLEX ELEGANCE MASSAT KL3	4035459DE1401C3K
200264	VENOFLEX ELEGANCE MASSAT/H KL1	4035459DE1401A3F
200265	VENOFLEX ELEGANCE MASSAT/H KL2	4035459DE1401B3H
200266	VENOFLEX ELEGANCE MASSAT/H KL3	4035459DE1401C3K
200274	VENOFLEX ELEGANCE MASSAT/U KL1	4035459DE1401A3F
200275	VENOFLEX ELEGANCE MASSAT/U KL2	4035459DE1401B3H
200276	VENOFLEX ELEGANCE MASSAT/U KL3	4035459DE1401C3K
2002A4	VENOFLEX ELEGANCE MASSAT/ES KL1	4035459DE1401A3F
2002A5	VENOFLEX ELEGANCE MASSAT/ES KL2	4035459DE1401B3H
2002A6	VENOFLEX ELEGANCE MASSAT/ES KL3	4035459DE1401C3K
2002B4	VENOFLEX ELEGANCE MASSAT/E KL1	4035459DE1401A3F
2002B5	VENOFLEX ELEGANCE MASSAT/E KL2	4035459DE1401B3H
2002B6	VENOFLEX ELEGANCE MASSAT/E KL3	4035459DE1401C3K
2002C4	VENOFLEX ELEGANCE MASSAT/UE KL1	4035459DE1401A3F
2002C5	VENOFLEX ELEGANCE MASSAT/UE KL2	4035459DE1401B3H
2002C6	VENOFLEX ELEGANCE MASSAT/UE KL3	4035459DE1401C3K



<b>Produktcode</b> <i>Product code</i>	<b>Produkt- oder Handelsname</b> <i>Product name</i>	<b>Basis UDI-DI</b> <i>Basic UDI-DI</i>
2002T1	VENOFLEX ELEGANCE MASSAD KL1	4035459DE1401A3F
2002T2	VENOFLEX ELEGANCE MASSAD KL2	4035459DE1401B3H
2002T3	VENOFLEX ELEGANCE MASSAD KL3	4035459DE1401C3K
2002U1	VENOFLEX ELEGANCE MASSAF KL1	4035459DE1401A3F
2002U2	VENOFLEX ELEGANCE MASSAF KL2	4035459DE1401B3H
2002U3	VENOFLEX ELEGANCE MASSAF KL3	4035459DE1401C3K
2002V1	VENOFLEX ELEGANCE MASSAG KL1	4035459DE1401A3F
2002V2	VENOFLEX ELEGANCE MASSAG KL2	4035459DE1401B3H
2002V3	VENOFLEX ELEGANCE MASSAG KL3	4035459DE1401C3K
2002X1	VENOFLEX ELEGANCE MASSAT KL1	4035459DE1401A3F
2002X2	VENOFLEX ELEGANCE MASSAT KL2	4035459DE1401B3H
2002X3	VENOFLEX ELEGANCE MASSAT KL3	4035459DE1401C3K
2002Y1	VENOFLEX ELEGANCE MASSATE KL1	4035459DE1401A3F
2002Y2	VENOFLEX ELEGANCE MASSATE KL2	4035459DE1401B3H
2002Y3	VENOFLEX ELEGANCE MASSATE KL3	4035459DE1401C3K



**Anhang II zur Konformitätserklärung**  
**vom 19. Mai 2021**  
*Appendix II of Declaration of Conformity*  
*of May 19<sup>th</sup> 2021*

<b>Produktcode</b> <i>Product code</i>	<b>Produkt- oder Handelsname</b> <i>Product name</i>	<b>Basis UDI-DI</b> <i>Basic UDI-DI</i>
30021A	VENOFLEX MICRO SERIE AD KKL.1	4035459DE1406A3W
30021B	VENOFLEX MICRO SERIE AD KKL.2	4035459DE1406B3Y
30023D	VENOFLEX MICRO SERIE AG KKL.1	4035459DE1406A3W
30023E	VENOFLEX MICRO SERIE AG KKL.2	4035459DE1406B3Y
30023G	VENOFLEX MICRO SERIE AG+ KKL.1	4035459DE1406A3W
30023H	VENOFLEX MICRO SERIE AG+ KKL.2	4035459DE1406B3Y
30025A	VENOFLEX MICRO SERIE AT KKL.1	4035459DE1406A3W
30025B	VENOFLEX MICRO SERIE AT KKL.2	4035459DE1406B3Y
30027A	VENOFLEX MICRO SERIE ATU KKL.1	4035459DE1406A3W
30027B	VENOFLEX MICRO SERIE ATU KKL.2	4035459DE1406B3Y
300214	VENOFLEX MICRO MASS AD KKL.1	4035459DE1405A3T
300215	VENOFLEX MICRO MASS AD KKL.2	4035459DE1405B3V
300217	VENOFLEX MICRO MASS AD KKL.1	4035459DE1405A3T
300218	VENOFLEX MICRO MASS AD KKL.2	4035459DE1405B3V
300224	VENOFLEX MICRO MASS AF KKL.1	4035459DE1405A3T
300225	VENOFLEX MICRO MASS AF KKL.2	4035459DE1405B3V
300227	VENOFLEX MICRO MASS AF KKL.1	4035459DE1405A3T
300228	VENOFLEX MICRO MASS AF KKL.2	4035459DE1405B3V
300234	VENOFLEX MICRO MASS AG KKL.1	4035459DE1405A3T
300235	VENOFLEX MICRO MASS AG KKL.2	4035459DE1405B3V
300237	VENOFLEX MICRO MASS AG KKL.1	4035459DE1405A3T



<b>Produktcode</b> <i>Product code</i>	<b>Produkt- oder Handelsname</b> <i>Product name</i>	<b>Basis UDI-DI</b> <i>Basic UDI-DI</i>
300238	VENOFLEX MICRO MASS AG KKL.2	4035459DE1405B3V
300244	VENOFLEX MICRO MASS AGHT KKL.1	4035459DE1405A3T
300245	VENOFLEX MICRO MASS AGHT KKL.2	4035459DE1405B3V
300254	VENOFLEX MICRO MASS AT KKL.1	4035459DE1405A3T
300255	VENOFLEX MICRO MASS AT KKL.2	4035459DE1405B3V
300264	VENOFLEX MICRO MASS ATH KKL.1	4035459DE1405A3T
300265	VENOFLEX MICRO MASS ATH KKL.2	4035459DE1405B3V
300274	VENOFLEX MICRO MASS ATU KKL.1	4035459DE1405A3T
300275	VENOFLEX MICRO MASS ATU KKL.2	4035459DE1405B3V
3002A4	VENOFLEX MICRO MASS ATE KKL.1	4035459DE1405A3T
3002A5	VENOFLEX MICRO MASS ATE KKL.2	4035459DE1405B3V
3002B4	VENOFLEX MICRO MASS ATE KKL.1	4035459DE1405A3T
3002B5	VENOFLEX MICRO MASS ATE KKL.2	4035459DE1405B3V

3002T1	VENOFLEX MICRO MASS AD KKL.1	4035459DE1405A3T
3002T2	VENOFLEX MICRO MASS AD KKL.2	4035459DE1405B3V
3002U1	VENOFLEX MICRO MASS AF KKL.1	4035459DE1405A3T
3002U2	VENOFLEX MICRO MASS AF KKL.2	4035459DE1405B3V
3002V1	VENOFLEX MICRO MASS AG KKL.1	4035459DE1405A3T
3002V2	VENOFLEX MICRO MASS AG KKL.2	4035459DE1405B3V
3002X1	VENOFLEX MICRO MASS AT KKL.1	4035459DE1405A3T
3002X2	VENOFLEX MICRO MASS AT KKL.2	4035459DE1405B3V
3002Y1	VENOFLEX MICRO MASS ATE KKL.1	4035459DE1405A3T
3002Y2	VENOFLEX MICRO MASS ATE KKL.2	4035459DE1405B3V



**Anhang III zur Konformitätserklärung  
vom 19. Mai 2021**

***Appendix II of Declaration of Conformity  
of May 19<sup>th</sup> 2021***

<b>Produktcode</b> <i>Product code</i>	<b>Produkt- oder Handelsname</b> <i>Product name</i>	<b>Basis UDI-DI</b> <i>Basic UDI-DI</i>
2002D2	2002 CG O. SCHULTERKAPPE KKL 2	4035459DE1403A3M
2002E2	2002 CG M. SCHULTERK.RE. KKL 2	4035459DE1403A3M
2002F2	2002 CG M. SCHULTERK.LI KKL 2	4035459DE1403A3M
2002D8	2002 CG O.SCHULTERK. M. HAFTB.	4035459DE1404A3Q
2002G5	2002 CG M.SCHULTERK. O.HAFTB.	4035459DE1404A3Q