

EU-KONFORMITÄTSERKLÄRUNG

EC DECLARATION OF CONFORMITY

gemäß der Richtlinie 93/42/EWG des Rates über Medizinprodukte Richtlinie
according to Council Directive 93/42/EEC concerning medical devices

**Name und Adresse
des Herstellers**
*Name and address of
the Company*

SEM Plastomed GmbH Medizin- und Kunststofftechnik
Schulstrasse 6 57612 Obererbach Deutschland

SRN Nr. SRN No. **DE-MF-000006401**

Wir erklären hiermit in alleiniger Verantwortung, daß die nachfolgend im Anhang gelisteten Medizinprodukte der Richtlinie 93/42/EWG (MDD) entsprechen und alle anwendbaren grundlegenden Anforderungen nach Anhang I erfüllt sind.

We declare under sole responsibility that the following medical devices listed in the appendix are in compliance with Directive 93/42/EEC (MDD) and fulfil all applicable essential requirements according Annex I.

Produktbezeichnung
Product Name

ABSAUGSCHLAUCH steril
SUCTION TUBE sterile

Basis UDI-DI
Basic UDI-DI

4046452AS-steril-
TD-01U4

Zweckbestimmung
Intended Use

Plastomed Absaugschläuche sind steriles, nicht-invasives medizinisches Zubehör für Vakuumsysteme, zur einmaligen Verwendung. Sie werden mit diversen Schlauchverbindungsstücken an den Sammelbehälter von Vakuumquellen angeschlossen und dienen mit diversen Endstücken zum Absaugen und Durchleiten von Flüssigkeiten, Feststoffen oder Gasen in den angeschlossenen Sammelbehälter des Vakuumsystems.

Plastomed Suction Tubes are sterile non-invasive single-use medical accessories for vacuum systems. Their various connectors can be connected to the collection container of the vacuum source and are used in combination with various end-pieces for conducting liquid, solid particles or gas into the collection container of the vacuum system.

UMDNS Code
16-779

GMDN Code
16779

Durchgeführtes Konformitätsbewertungsverfahren nach Anhang
*performed Conformity assessment
Procedure according Annex*

V

der Richtlinie 93/42/EWG
of Directive 93/42/EEC

**Risiko-
klasse**
Risk Class

Is

Regel 1
Rule 1

Hinzugezogene Benannte Stelle
Notified Body consulted

0197

TÜV Rheinland LGA Products GmbH
Reg.-Nr. ZLG-BS-242.10.10

EG Zertifikat Nr. / EC Certificate No. DD 60130186 001

Ort, Datum / place, date

Holger Schmid
(Geschäftsführer/CEO)
SEM Plastomed GmbH

Diese Erklärung ist bis zum 31.12.2027 gültig.

This declaration is valid until 31.12.2027.

Anhang zur EU-Konformitätserklärung

Appendix to the EC Declaration of Conformity

ABSAUGSCHLAUCH steril
SUCTION TUBE sterile

Folgende Produkte sind Gegenstand der EU-Konformitätserklärung:
 The following products are subject of the EC declaration of conformity:

Technische Dokumentation
 Technical Documentation

TDAS

UDI-DI	REF	UDI-DI	REF	UDI-DI	REF
04046452001185	AS-030-30 S	04046452009136	AS-240-30 LLS	04046452202049	AS-210-25 TbTbS
04046452001192	AS-060-30 S	04046452009365	AS-300-25 LLS	04046452202124	AS-210-30 TbTbS
04046452001178	AS-100-25 S	04046452009143	AS-300-30 LLS	04046452008474	AS-240-25 TbTbS
04046452001017	AS-150-25 S	04046452009761	AS-350-25 LLS	04046452008498	AS-240-30 TbTbS
04046452006036	AS-150-30 S	04046452011887	AS-350-30 LLS	04046452202063	AS-300-25 TbTbS
04046452006753	AS-180-25 S	04046452010354	AS-400-25 LLS	04046452202148	AS-300-30 TbTbS
04046452001109	AS-180-30 S	04046452010378	AS-400-30 LLS	04046452009860	AS-350-25 TbTbS
04046452007316	AS-200-25 S	04046452006500	AS-150-25 TS	04046452009884	AS-350-30 TbTbS
04046452007330	AS-200-30 S	04046452000591	AS-150-30 TS	04046452010453	AS-400-25 TbTbS
04046452001048	AS-210-25 S	04046452002021	AS-180-25 TS	04046452010477	AS-400-30 TbTbS
04046452001123	AS-210-30 S	04046452007170	AS-180-30 TS	04046452011399	AS-130-27 TFS
04046452008399	AS-240-25 S	04046452002038	AS-200-25 TS	04046452002489	AS-130-30 TFS
04046452008412	AS-240-30 S	04046452002175	AS-200-27 TS	04046452000010	AS-150-25 TFS
04046452001215	AS-250-25 S	04046452007750	AS-200-30 TS	04046452000096	AS-150-30 TFS
04046452001260	AS-300-25 S	04046452008238	AS-210-25 TS	04046452000027	AS-180-25 TFS
04046452001147	AS-300-30 S	04046452008252	AS-210-30 TS	04046452006852	AS-180-30 TFS
04046452009785	AS-350-25 S	04046452002052	AS-240-25 TS	04046452000034	AS-200-25 TFS
04046452009808	AS-350-30 S	04046452009037	AS-240-30 TS	04046452000119	AS-200-30 TFS
04046452010392	AS-400-25 S	04046452002199	AS-290-27 TS	04046452000041	AS-210-25 TFS
04046452010415	AS-400-30 S	04046452002069	AS-300-25 TS	04046452008054	AS-210-30 TFS
04046452004179	AS-130-30 FS	04046452316067	AS-300-25 TS-soft	04046452000058	AS-240-25 TFS
04046452005978	AS-150-25 FS	04046452002182	AS-300-27 TS	04046452008672	AS-240-30 TFS
04046452004018	AS-150-30 FS	04046452009686	AS-300-30 TS	04046452000065	AS-300-25 TFS
04046452006692	AS-180-25 FS	04046452002076	AS-350-25 TS	04046452000171	AS-300-27 TFS
04046452004100	AS-180-30 FS	04046452010279	AS-350-30 TS	04046452011436	AS-300-30 TFS
04046452007279	AS-200-25 FS	04046452010873	AS-400-25 TS	04046452010217	AS-350-25 TFS
04046452004117	AS-200-30 FS	04046452002243	AS-400-27 TS	04046452009945	AS-350-30 TFS
04046452007873	AS-210-25 FS	04046452010897	AS-400-30 TS	04046452011412	AS-400-25 TFS
04046452007897	AS-210-30 FS	04046452006050	AS-150-25 TbFS	04046452010538	AS-400-30 TFS
04046452008337	AS-240-25 FS	04046452006074	AS-150-30 TbFS	04046452003301	AS-500-25 TFS
04046452008351	AS-240-30 FS	04046452203022	AS-180-25 TbFS	04046452001987	AS-600-25 TFS
04046452009327	AS-300-25 FS	04046452006777	AS-180-30 TbFS	04046452006142	AS-150-25 TFLS
04046452009341	AS-300-30 FS	04046452203039	AS-200-25 TbFS	04046452006166	AS-150-30 TFLS
04046452009723	AS-350-25 FS	04046452007354	AS-200-30 TbFS	04046452008023	AS-180-25 TFLS
04046452009747	AS-350-30 FS	04046452007958	AS-210-25 TbFS	04046452006838	AS-180-30 TFLS
04046452010316	AS-400-25 FS	04046452007972	AS-210-30 TbFS	04046452007415	AS-200-25 TFLS
04046452010330	AS-400-30 FS	04046452008436	AS-240-25 TbFS	04046452007439	AS-200-30 TFLS
04046452009174	AS-090-25 LLS	04046452008450	AS-240-30 TbFS	04046452007996	AS-210-25 TFLS
04046452009181	AS-100-25 LLS	04046452009389	AS-300-25 TbFS	04046452008016	AS-210-30 TFLS
04046452005992	AS-150-25 LLS	04046452009402	AS-300-30 TbFS	04046452008634	AS-240-25 TFLS
04046452006012	AS-150-30 LLS	04046452009822	AS-350-25 TbFS	04046452008658	AS-240-30 TFLS
04046452006715	AS-180-25 LLS	04046452009846	AS-350-30 TbFS	04046452009426	AS-300-25 TFLS
04046452006739	AS-180-30 LLS	04046452010439	AS-400-30 TbFS	04046452009440	AS-300-30 TFLS
04046452009150	AS-200-25 LLS	04046452202018	AS-150-25 TbTbS	04046452009907	AS-350-25 TFLS
04046452007293	AS-200-30 LLS	04046452006128	AS-150-30 TbTbS	04046452009921	AS-350-30 TFLS
04046452007910	AS-210-25 LLS	04046452006791	AS-180-25 TbTbS	04046452010491	AS-400-25 TFLS
04046452007934	AS-210-30 LLS	04046452006814	AS-180-30 TbTbS	04046452010514	AS-400-30 TFLS
04046452008375	AS-240-25 LLS	04046452007378	AS-200-25 TbTbS	04046452011368	AS-100-30 TgS
		04046452007392	AS-200-30 TbTbS	04046452006388	AS-150-25 TgS

UDI-DI	REF	UDI-DI	REF	UDI-DI	REF
04046452209093	AS-150-30 TgS	04046452006289	AS-150-30 TgLS	04046452207181	AS-600-25 TgTgS
04046452209024	AS-180-25 TgS	04046452006937	AS-180-25 TgLS	04046452207198	AS-600-30 TgTgS
04046452006975	AS-180-30 TgS	04046452006951	AS-180-30 TgLS	04046452006340	AS-150-25 TgTks
04046452007538	AS-200-25 TgS	04046452007491	AS-200-25 TgLS	04046452006364	AS-150-30 TgTks
04046452007552	AS-200-30 TgS	04046452007514	AS-200-30 TgLS	04046452007019	AS-180-25 TgTks
04046452209048	AS-210-25 TgS	04046452206047	AS-210-25 TgLS	04046452007033	AS-180-30 TgTks
04046452008115	AS-210-30 TgS	04046452206122	AS-210-30 TgLS	04046452007576	AS-200-25 TgTks
04046452008795	AS-240-25 TgS	04046452010118	AS-240-25 TgLS	04046452007590	AS-200-30 TgTks
04046452008818	AS-240-30 TgS	04046452008771	AS-240-30 TgLS	04046452211041	AS-210-25 TgTks
04046452209062	AS-300-25 TgS	04046452206061	AS-300-25 TgLS	04046452008139	AS-210-30 TgTks
04046452209178	AS-300-30 TgS	04046452009525	AS-300-30 TgLS	04046452008856	AS-240-25 TgTks
04046452209147	AS-300-30 TgS-soft	04046452010002	AS-350-25 TgLS	04046452008870	AS-240-30 TgTks
04046452010057	AS-350-25 TgS	04046452010033	AS-350-30 TgLS	04046452211065	AS-300-25 TgTks
04046452010071	AS-350-30 TgS	04046452206085	AS-400-25 TgLS	04046452009549	AS-300-30 TgTks
04046452010651	AS-400-25 TgS	04046452010637	AS-400-30 TgLS	04046452211072	AS-350-25 TgTks
04046452010675	AS-400-30 TgS	04046452006555	AS-150-25 TgTS	04046452010095	AS-350-30 TgTks
04046452006227	AS-150-25 TgFS	04046452208096	AS-150-30 TgTS	04046452010699	AS-400-25 TgTks
04046452006241	AS-150-30 TgFS	04046452007057	AS-180-25 TgTS	04046452010712	AS-400-30 TgTks
04046452205026	AS-180-25 TgFS	04046452007071	AS-180-30 TgTS	04046452010972	AS-500-25 TgTks
04046452006913	AS-180-30 TgFS	04046452007613	AS-200-25 TgTS	04046452320026	AS-180-25 Tks
04046452205033	AS-200-25 TgFS	04046452007637	AS-200-30 TgTS	04046452204173	AS-050-25 TkFS
04046452007477	AS-200-30 TgFS	04046452008153	AS-210-25 TgTS	04046452006401	AS-150-25 TkFS
04046452205040	AS-210-25 TgFS	04046452208126	AS-210-30 TgTS	04046452006425	AS-150-30 TkFS
04046452008092	AS-210-30 TgFS	04046452008894	AS-240-25 TgTS	04046452204029	AS-180-25 TkFS
04046452008733	AS-240-25 TgFS	04046452008917	AS-240-30 TgTS	04046452007095	AS-180-30 TkFS
04046452008757	AS-240-30 TgFS	04046452009266	AS-260-25 TgTS	04046452007651	AS-200-25 TkFS
04046452205170	AS-250-25 TgFS	04046452009563	AS-300-30 TgTS	04046452007675	AS-200-30 TkFS
04046452009488	AS-300-25 TgFS	04046452200243	AS-300-30 TgTS-soft	04046452008177	AS-210-25 TkFS
04046452009501	AS-300-30 TgFS	04046452208072	AS-350-25 TgTS	04046452008191	AS-210-30 TkFS
04046452205071	AS-350-25 TgFS	04046452010132	AS-350-30 TgTS	04046452008931	AS-240-25 TkFS
04046452009983	AS-350-30 TgFS	04046452010736	AS-400-25 TgTS	04046452008955	AS-240-30 TkFS
04046452010590	AS-400-25 TgFS	04046452010750	AS-400-30 TgTS	04046452009587	AS-300-25 TkFS
04046452010613	AS-400-30 TgFS	04046452314148	AS-300-30 TgTbS	04046452009600	AS-300-30 TkFS
04046452006180	AS-150-25 TgFLS	04046452006302	AS-150-25 TgTgS	04046452010156	AS-350-25 TkFS
04046452006203	AS-150-30 TgFLS	04046452006326	AS-150-30 TgTgS	04046452010170	AS-350-30 TkFS
04046452006876	AS-180-25 TgFLS	04046452207020	AS-180-25 TgTgS	04046452010774	AS-400-25 TkFS
04046452006890	AS-180-30 TgFLS	04046452006999	AS-180-30 TgTgS	04046452010798	AS-400-30 TkFS
04046452007453	AS-200-30 TgFLS	04046452207037	AS-200-25 TgTgS	04046452006449	AS-150-25 TkTbS
04046452008078	AS-210-30 TgFLS	04046452207112	AS-200-30 TgTgS	04046452011474	AS-150-30 TkTbS
04046452008696	AS-240-25 TgFLS	04046452207044	AS-210-25 TgTgS	04046452007118	AS-180-25 TkTbS
04046452008719	AS-240-30 TgFLS	04046452207129	AS-210-30 TgTgS	04046452007699	AS-200-25 TkTbS
04046452212178	AS-250-25 TgFLS	04046452207259	AS-210-30 TgTgS-soft	04046452011498	AS-200-30 TkTbS
04046452212062	AS-300-25 TgFLS	04046452207051	AS-240-25 TgTgS	04046452200045	AS-210-25 TkTbS
04046452009464	AS-300-30 TgFLS	04046452008832	AS-240-30 TgTgS	04046452011511	AS-210-30 TkTbS
04046452212079	AS-350-25 TgFLS	04046452207068	AS-300-25 TgTgS	04046452008979	AS-240-25 TkTbS
04046452009969	AS-350-30 TgFLS	04046452207211	AS-300-25 TgTgS-soft	04046452011535	AS-240-30 TkTbS
04046452010552	AS-400-25 TgFLS	04046452207143	AS-300-30 TgTgS	04046452200175	AS-270-25 TkTbS
04046452010576	AS-400-30 TgFLS	04046452207266	AS-300-30 TgTgS-soft	04046452200182	AS-270-30 TkTbS
04046452311000	AS-180-30 TgKS-soft	04046452207075	AS-350-25 TgTgS	04046452009624	AS-300-25 TkTbS
04046452011900	AS-180-25 TgKS	04046452207150	AS-350-30 TgTgS	04046452009648	AS-300-30 TkTbS
04046452005411	AS-210-25 TgKS	04046452000379	AS-400-25 TgTgS	04046452200199	AS-300-30 TkTbS-soft
04046452311024	AS-300-25 TgKS	04046452207167	AS-400-30 TgTgS	04046452010194	AS-350-25 TkTbS
04046452006265	AS-150-25 TgLS	04046452207204	AS-500-25 TgTgS-soft	04046452010231	AS-350-30 TkTbS

UDI-DI	REF	UDI-DI	REF	UDI-DI	REF
04046452200083	AS-400-25 TkTbS	04046452010255	AS-350-30 TkTks	04046452003202	AS-300-27 TTS
04046452010811	AS-400-30 TkTbS	04046452010835	AS-400-25 TkTks	04046452000157	AS-300-30 TTS
04046452006463	AS-150-25 TkTks	04046452010859	AS-400-30 TkTks	04046452003073	AS-350-25 TTS
04046452006487	AS-150-30 TkTks	04046452003233	AS-030-25 TTS	04046452003158	AS-350-30 TTS
04046452212031	AS-180-25 TkTkFLS	04046452003011	AS-150-25 TTS	04046452011450	AS-400-25 TTS
04046452201042	AS-210-25 TkTkFLS	04046452006531	AS-150-30 TTS	04046452010910	AS-400-30 TTS
04046452007132	AS-180-25 TkTks	04046452003028	AS-180-25 TTS	04046452003141	AS-600-25 TTS
04046452007156	AS-180-30 TkTks	04046452007194	AS-180-30 TTS	04046452003615	851/12206
04046452007712	AS-200-25 TkTks	04046452003035	AS-200-25 TTS	04046452005824	AS-160/90 TgFLS
04046452007736	AS-200-30 TkTks	04046452003219	AS-200-27 TTS	04046452315121	AS-180-21 Tk/K/KL/S
04046452201042	AS-210-25 TkTks	04046452007774	AS-200-30 TTS	04046452003691	AS-180-21 Tk/LB/KL/S
04046452008214	AS-210-30 TkTks	04046452003042	AS-210-25 TTS	04046452003561	AS-180-25 T/K/MLL/S
04046452008993	AS-240-25 TkTks	04046452008276	AS-210-30 TTS	04046452003592	AS-180-30 T/K/KL/S
04046452009013	AS-240-30 TkTks	04046452003059	AS-240-25 TTS	04046452313004	AS-240-25 TgTgKS
04046452201066	AS-300-25 TkTks	04046452003196	AS-240-27 TTS	04046452285400	AS-400-0408 Tks
04046452009662	AS-300-30 TkTks	04046452009051	AS-240-30 TTS	04046452002168	AS-400-0408 TkTks
04046452201172	AS-300-30 TkTks-soft	04046452009280	AS-260-25 TTS	04046452000935	AS-400-0610 Tks
04046452201073	AS-350-25 TkTks	04046452003066	AS-300-25 TTS	04046452312007	AS-420-30 KS