Declaration of Firm Quality System and Continuity

We, as ***Aditus Medical GmbH*** located in ***Kurfürstendamm 224 10719 Berlin / GERMANY,*** declare that our products that are manufactured by ***Aditus Medical GmbH***, and whose model, classification according to 93/42/EEC Medical Devices Directive Annex IX rule 8 class IIb are audited for their conformity according to Annex II of 93/42/EEC Medical Devices Directive(with the exemption section 4),full quality assurance, and GMDN codes are provided below, are manufactured in conformity with the standards and European Union Regulations;

Medical Devices Directive 93/42/EEC Annex II (with the exemption section 4), full quality assurance, is selected as Conformity Assessment Route.

EN ISO 13485:2016 ***Quality Management System,***

93/42 EEC	EN ISO 10993-13: 2010	ISO 14644-4: 2001
EN ISO 13485:2016	EN ISO 10993-17: 2009	ISO 14644-5: 2004
EN ISO 14971: 2019	EN ISO 10993-18: 2009	ISO 14644-7: 2004
EN ISO 24971: 2020	ISO 11135 : 2014	ISO 14937: 2009
EN 1041:2015	EN ISO 11138-1: 2017	EN ISO 15223-1:2016
EN ISO 10993-1: 2020	EN ISO 11138-2: 2017	EN 62366+A1;2015
EN ISO 10993-3: 2014	EN ISO 11140-1: 2014	Meddev 2.12-1 rev.8: 2013
EN ISO 10993-5: 2009	EN ISO 11607-1: 2019	Meddev 2.12-2 Rev 2: 2012
EN ISO 10993-6: 2016	EN ISO 11607-2: 2019	Meddev 2.7.1 Rev 4
EN ISO 10993-7: 2008	EN ISO 11737-1: 2018	NBOG_BPG 2010_1
ISO 10993-8: 2000	EN ISO 11737-2: 2019	NBOG_BPG 2014_3
EN ISO 10993-9: 2009	EN ISO 14630: 2009	ISO 17664: 2017
ISO 10993-10: 2014	ISO 14644-1: 2015	
ISO 10993-11: 2017	ISO 14644-2: 2015	
ISO 10993-12: 2012	ISO 14644-3: 2019	

We declare that all requirements of the quality system of product which is produced in conformity with standards and European Union Regulations mentioned above will be fulfilled, quality system will be applied completely and effectively, a system will be maintained, the required corrective actions are performed like it is indicated 93/42/EEC Medical Devices Directive-Annex II (with the exemption section 4, full quality assurance section).

Digitally signed by Jighili Tatiana
Date: 2025.01.17 13:51:10 EET
Reason: MoldSign Signature
Location: Moldova
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Product Name	Model Name	Class	Rule	GMDN Code	Lot No	Production Date	Expiry Date	Shelf Life
BONE CEMENT	CEMAD S40 Standart Viscosity Bone Cement CEMAD LV Vertebral Radiopaque Bone Cement	IIb	8	35217	B04003LB0301	04.2019	04.2022	Three years

The products are under our sole responsibility. The conformity of our products with the directives and documents above are approved with the certificate, for which information is provided below, by the notified body ***National Evaluation Center Of Quality and Technology In Health S.A.(EKAPTY), (notified body number:0653),*** located in ***13-15 Smyrnis, 165 62 Glyfada- GREECE.***

We hereby declare that the above mentioned bone cement product is manufacture according to Class IIb, Rule 8 of Annex IX of Medical Device Directive 93/42 / EEC, EN ISO 13485:2016, EN ISO 9001:2015, EN ISO 5833:2002

Certificate No	:	302031565
Certificate Issue Date	:	05/04/2021
Certificate Valid Date	:	24/05/2024
Certificate Revision Date	:	-

Approved By	:	Ahmet ERDEM
Title	:	General Manager
Issue Date	:	15.07.2016
Issue Place	:	Berlin, GERMANY
Declaration Revision No	:	10
Declaration Revision Date	:	20.04.2021

Signature

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Aditus Medical GmbH
c/o Final Treuhand u. Verwaltungs GmbH
Kurfürstendamm 224
10719 Berlin
Tel.: 030 - 890 652 44 / -55
Fax.:030 - 890 448 78

EC DECLARATION of CONFORMITY

We, as ***Aditus Medical GmbH*** at ***Kurfürstendamm 224 10719 Berlin / GERMANY,*** hereby declare that; our products models that are manufactured, with risk class IIb according to the 93/42/EEC Medical Devices Directive ANNEX IX rule 8 and with given GMDN codes are produced in conformity with the following standards and European Union Regulations. All supporting documentation is retained under the premises of our company,

All provisions of 93/42/EEC Medical Device Directive,

93/42 EEC	**EN ISO 10993-13: 2010**	**ISO 14644-4: 2001**
EN ISO 13485:2016	**EN ISO 10993-17: 2009**	**ISO 14644-5: 2004**
EN ISO 14971: 2019	**EN ISO 10993-18: 2009**	**ISO 14644-7: 2004**
EN ISO 24971: 2020	**ISO 11135 : 2014**	**ISO 14937: 2009**
EN 1041:2015	**EN ISO 11138-1: 2017**	**EN ISO 15223-1:2016**
EN ISO 10993-1: 2020	**EN ISO 11138-2: 2017**	**EN 62366+A1;2015**
EN ISO 10993-3: 2014	**EN ISO 11140-1: 2014**	**Meddev 2.12-1 rev.8: 2013**
EN ISO 10993-5: 2009	**EN ISO 11607-1: 2019**	**Meddev 2.12-2 Rev 2: 2012**
EN ISO 10993-6: 2016	**EN ISO 11607-2: 2019**	**Meddev 2.7.1 Rev 4**
EN ISO 10993-7: 2008	**EN ISO 11737-1: 2018**	**NBOG_BPG 2010_1**
ISO 10993-8: 2000	**EN ISO 11737-2: 2019**	**NBOG_BPG 2014_3**
EN ISO 10993-9: 2009	**EN ISO 14630: 2009**	**ISO 17664: 2017**
ISO 10993-10: 2014	**ISO 14644-1: 2015**	
ISO 10993-11: 2017	**ISO 14644-2: 2015**	
ISO 10993-12: 2012	**ISO 14644-3: 2019**	

Medical Devices Directive 93/42/EEC Annex II (with the exemption section 4), full quality assurance, is selected as Conformity Assessment Route.

Product Name	Model Name	Class	Rule	GMDN Code	Lot No	Production Date	Expiry Date	Shelf Life
BONE CEMENT	CEMAD S40 Standart Viscosity Bone Cement CEMAD LV Vertebral Radiopaque Bone Cement	II b	8	35217	B04003LB0301	04.2019	04.2022	Three years

The conformity of our products to the directives and documents mentioned above is confirmed by the notified body ***National Evaluation Center Of Quality and Technology In Health S.A.(EKAPTY)(notified body number:0653), (Address:13-15 Smyrnis, 165 62 Glyfada- GREECE)*** with the European Commission Product Conformity Certificate for which the details are given below:

We hereby declare that the above mentioned bone cement product is manufacture according to Class IIb, Rule 8 of Annex IX of Medical Device Directive 93/42 / EEC, EN ISO 13485:2016, EN ISO 9001:2015, EN ISO 5833:2002.

Certificate No	:	302031565
Certificate Issue Date	:	05/04/2021
Certificate Valid Date	:	24/05/2024
Certificate Revision Date	:	-

Approved By	:	Ahmet ERDEM
Title	:	General Manager
Issue Date	:	15.07.2016
Issue Place	:	Berlin, GERMANY
Declaration Revision No	:	10
Declaration Revision Date	:	20.04.2021

Signature

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Aditus Medical GmbH
c/o Final Treuhand u. Verwaltungs GmbH
Kurfürstendamm 224
10719 Berlin
Tel.: 030 - 890 652 44 / -55
Fax.: 030 - 890 448 78

PRODUCT LIST

1. BONE CEMENT

1.1. CEMAD

Item No	Reference Code	Product Description
1	ADCEMH	CEMAD-H High Viscosity Bone Cement
2	ADCEMLV	CEMAD-LV Low Viscosity Bone Cement
3	ADCEMS20	CEMAD-S20 Standard Viscosity Bone Cement
4	ADCEMS40	CEMAD-S40 Standard Viscosity Bone Cement
5	ADCEMS60	CEMAD-S60 Standard Viscosity Bone Cement

1.2. PAR

Item No	Reference Code	Product Description
1	PARH	PAR-H High Viscosity Bone Cement
2	PARLV	PAR-LV Low Viscosity Bone Cement
3	PARS20	PAR-S20 Standard Viscosity Bone Cement
4	PARS40	PAR-S40 Standard Viscosity Bone Cement
5	PARS60	PAR-S60 Standard Viscosity Bone Cement

1.3. ACEM

Item No	Reference Code	Product Description
1	ACEMH	A-CEM-H High Viscosity Bone Cement
2	ACEMLV	A-CEM-LV Low Viscosity Bone Cement
3	ACEMS20	A-CEM-S20 Standard Viscosity Bone Cement
4	ACEMS40	A-CEM-S40 Standard Viscosity Bone Cement
5	ACEMS60	A-CEM-S60 Standard Viscosity Bone Cement

1.4. KCEM

Item No	Reference Code	Product Description
1	KCEMH	K-CEM-H High Viscosity Bone Cement
2	KCEMLV	K-CEM-LV Low Viscosity Bone Cement
3	KCEMS20	K-CEM-S20 Standard Viscosity Bone Cement
4	KCEMS40	K-CEM-S40 Standard Viscosity Bone Cement
5	KCEMS60	K-CEM-S60 Standard Viscosity Bone Cement