

## ARTICLE 12 DECLARATION CUSTOM PROCEDURE TRAYS

We hereby declare that the distributed Custom Procedure Trays, specified in the annexed product list, are covered by the "**Production Quality Assurance Certificate**", reference number: **CE 567925** issued on **December 1, 2010**, delivered by **BSI**, Milton Keynes, United Kingdom and are in accordance with **Annex V** of the "**EC-Directive**", the Council Directive **93/42/EEC** of 14 June 1993, concerning medical devices, and Article 12 of this Council Directive.

Medica Europe has verified the mutual compatibility of the devices in accordance with the manufacturers' instructions and has carried out his operations in accordance with these instructions.

Medica Europe has packaged the Custom Procedure Trays and supplied relevant information to users incorporating relevant instructions from the manufacturers.

Sterilisation parameters have been agreed with the manufacturers of the devices.

The whole activity at Medica Europe is subjected to appropriate methods of internal control and inspection.

This declaration is supported by the Quality System certification based on the harmonized standard **EN ISO 13485:2003** Quality System Certificates with reference number: **MD 567141** issued on December 1, 2010 and delivered by **BSI**.

This Article 12 declaration covers all Custom Procedure Trays as specified in the product list belonging to this declaration, and is valid for all products manufactured at the following site(s):

Medica Europe BV  
Galliërsweg 20  
5349 AT OSS  
The Netherlands

Oss,

11 September 2014

B. Kreekels  
Manager Purchasing & Logistics /  
Quality Assurance and Regulatory Affairs



PRODUCT LIST

<b>Artnr</b>	<b>Description</b>	<b>Added</b>
259170F	PACK SELDINGER	20-06-2003
258366C	TRAY CORONAIR	14-11-2003
2586790	EXTRACTIESET	04-11-2005
100676AA	ANGIOTRAY	15-06-2006
100876AA	PACK CUN HEMODINAMICA	24-07-2006
100521AB	PACK PACEMAKER	05-10-2006
259172AB	PACK CVC	20-11-2006
102199AB	VALVOLA AORTIC-MITRALIC	29-08-2007
102425AA	PACK SELDINGER	09-10-2007
102866AA	PACK RADIO	15-04-2008
103118AA	PACK RADIO	06-05-2008
103527AA	PACK RADIO	10-06-2008
103916aa	PACK DIAGNOSTICO ESTAV	11-09-2008
104367AA	PACK ANGIO	09-12-2008
102198AD	BY PASS PACK	16-12-2008
104451AA	PACK DIAGNOST	27-01-2009
104499AB	PACK	16-02-2009
101977AE	HARTEXPLANTATIE FASE 3	17-03-2009
104585AB	GANGRETTES RADIO	01-04-2009
103860AC	CTS TRAY	07-04-2009
103861AB	OOGLEDEN TRAY	07-04-2009
104436AB	CARDIO PACK	14-04-2009
104909AA	KIT PACE-MAKER	14-04-2009
102492AD	HCK PACK	15-04-2009
102532AB	PUNCTIE SET	12-05-2009
102814AF	CV SET	12-05-2009
102997AE	TREPANATIESET ME	08-06-2009
104719AC	FLEBO TRAY	08-07-2009
101157AF	SECTIO TRAY	20-07-2009
102808AD	PACK RADIO	20-07-2009
104377AA	PACK RADIO	21-07-2009
102667AD	TOTALE HEUP TRAY	03-08-2009
105554AA	INBRENGSET SEPERAAT 8F	07-12-2009
105715AA	INTRODUCERSET BIJ INBRENGSET	14-12-2009
105643AA	ELECTROFYSIOLOGIE 2	22-12-2009
102240AE	CYSTO 004	04-01-2010
105723AA	PACK ANGIO FEM	11-01-2010
100058AE	ANGIOGRAPHIE	12-01-2010
105843AA	GROOT BASIS TRAY TEST	01-02-2010
103297AC	SECTIO (KC SPECIFIEK)	22-02-2010
105657AA	PACK PACEMAKER	15-03-2010
102831AG	ANGIOGRAFIESET	25-03-2010
105798AA	ANGIO PACK	31-03-2010
100926AJ	KNIE/SCHOUDE PAKKET	12-04-2010
101189AK	TOTALE HEUPPROTHESE TRAY	19-05-2010
103981AF	VARICES TRAY	19-05-2010
105060AB	PACK RADIO	19-05-2010
106077AB	ARTHROSCOPIE KNIE	20-05-2010
103967AG	GROOT BASIS TRAY	27-05-2010
103973AF	RECTUM TRAY	27-05-2010
103989AE	EXTENSIE TRAY	27-05-2010

105635AD	SET CESARIENNE EUR	10-06-2010
105958AC	SURGERY PACK FOR CHUAC	10-06-2010
102887AC	CATH PACK	20-09-2010
102891AD	PACK PACEMAKER	20-09-2010
102393AB	PACK CARDIO	23-09-2010
104611AH	ROBOT TRAY	28-09-2010
106217AB	SECTIO TRAY	05-10-2010
100905AH	VSM PAKKET	07-10-2010
100911AL	HEUP PAKKET	11-10-2010
100912AH	SCHOUDER KLEIN PAKKET	11-10-2010
100915AH	SHUNT PAKKET	11-10-2010
100966AJ	ARTHROSCOPIE PAKKET	11-10-2010
106245AC	VNUS TRAY	18-10-2010
105645AD	CARDIO	19-10-2010
100903AH	LAPAROSCOPIE PAKKET	27-10-2010
100906AI	LIESBREUK PAKKET	27-10-2010
101438AI	CRANIOTOMIEPAKKET	01-11-2010
100926AL	KNIE/SCHOUDER PAKKET	22-11-2010
102998AC	TREPANATIE SET	06-12-2010
102043AF	ARTHROSCOPIE TRAY	14-12-2010
105016AB	TEP TRAY	20-12-2010
102429AD	PACK HARTCATHETERISATIE	05-01-2011
103975AH	BASIS ENDO TRAY EURO	18-01-2011
106553AA	TOTALE KNIE TRAY	24-01-2011
106774AA	RAD/FEM SET	28-02-2011
100514AI	RFF TRAY	14-03-2011
105009AC	GASTRIC BYPASS/SLEEVE	14-03-2011
105011AC	AORTA STENT TRAY	14-03-2011
106568AB	KIT CRANIO BASE	21-03-2011
103463AF	VASECTOMIE PAKKET	21-03-2011
106567AB	KIT COLONNA	21-03-2011
106569AA	KIT MINICRANICO	21-03-2011
106828AB	CORO SET	28-03-2011
102212AF	PACK CARDIO	14-04-2011
104587AF	RADIOLOGIE	21-04-2011
106679AD	VNUS TRAY VERSIE 1	26-04-2011
103715AD	TRAY HEUP	27-04-2011
106999AA	CARDANGIOGRAPHIESET	28-04-2011
103737AD	TRAY EXTENSIE	02-05-2011
105848AC	TRAY TOTALE KNIE	04-05-2011
102095AE	TRAY MAMMA	05-05-2011
105845AB	EXTRACTIESET	05-05-2011
101400AG	BYPASS TRAY	11-05-2011
105014AB	PERIFERE VAAT TRAY	16-05-2011
106886AC	ANGIOGRAPHY SET	23-05-2011
103965AI	RUG	26-05-2011
105804AF	HEUPFRACTUUR	26-05-2011
106496AD	PACEMAKER	26-05-2011
106338AC	VARICES TRAY	31-05-2011
106503AE	VAAT TRAY	06-06-2011
106510AC	SECTIO TRAY	06-06-2011
106526AC	NEURO TRAY	06-06-2011
106516AD	MAMMA TRAY	08-06-2011
106543AC	OPEN SCHOUDER TRAY	08-06-2011
101992AF	HEUPSET COMPLEET	14-06-2011

105314AG	VAAT TRAY	16-06-2011
102867AF	TRAY HEUP	21-06-2011
103738AE	TRAY SECTIO	21-06-2011
100901AK	SECTIO PAKKET	11-07-2011
100959AI	KNO NEUS PAKKET	11-07-2011
102990AI	KNIEPROTHESE	11-07-2011
103080AF	VOET PAKKET	11-07-2011
106860AA	HCK PACK MET GW,INTROD.	11-07-2011
106942AB	LIESTAL CORO-SET	11-07-2011
103983AF	SECTIO TRAY	08-08-2011
106500AE	GROTE PROCEDURE TRAY	23-08-2011
106506AD	VKB TRAY	23-08-2011
106519AE	TOTALE KNIE TRAY	23-08-2011
106830AD	SCHOUDER SCOPIE TRAY	29-08-2011
107005AB	HUEFT-KNIE-TP-SET	21-09-2011
101400AH	BYPASS TRAY	04-10-2011
103737AF	TRAY EXTENSIE	05-10-2011
107122AC	CVC SET	05-10-2011
103738AG	SECTIO TRAY	06-10-2011
102867AI	TOTALE HEUP TRAY	13-10-2011
101855AF	PACK ANGIO/HEMODINAMICA	24-10-2011
103043AD	PACK CARDIO	24-10-2011
100926AM	KNIE/SCHOUDER PAKKET	03-11-2011
105848AF	TRAY TOTALE KNIE	09-11-2011
101992AI	HEUP COMPLEET TRAY	10-11-2011
102095AH	TRAY MAMMA	10-11-2011
100959AJ	KNO NEUS PAKKET	15-11-2011
107607AA	CORO-SET	24-11-2011
107359AB	PACEMAKERSET	06-12-2011
107122AD	CVC SET	12-12-2011
105848AG	TRAY TOTALE KNIE	15-12-2011
102393AC	PACK CARDIO	19-12-2011
102867AJ	TOTALE HEUP TRAY	19-12-2011
106815AB	EVAR TRAY	19-12-2011
106830AH	OPEN SCHOUDER TRAY	02-01-2012
103860AH	VASECTOMIE PAKKET	03-01-2012
103861AF	POLI EXTREMITEITEN TRAY	03-01-2012
103862AF	OOGLEDEN TRAY	03-01-2012
106500AG	GROTE PROCEDURE TRAY	03-01-2012
106507AF	HEUP TRAY	03-01-2012
100911AM	HEUP PAKKET	05-01-2012
106506AE	VKB TRAY	10-01-2012
106516AE	MAMMA TRAY	10-01-2012
106519AF	TOTALE KNIE TRAY	10-01-2012
106543AD	OPEN SCHOUDER TRAY	10-01-2012
107229AA	CVC TRAY ICU	10-01-2012
107583AA	EXTENSIE TRAY	10-01-2012
103715AE	TRAY HEUP	19-01-2012
105009AD	GASTRIC BYPASS/SLEEVE TRAY	19-01-2012
103705AC	TRAY EXTENSIE	23-01-2012
105011AD	AORTA STENT TRAY	23-01-2012
105014AC	PERIFERE VAAT TRAY	23-01-2012
105016AC	TEP TRAY	23-01-2012
106526AD	NEURO TRAY	30-01-2012
103527AB	PACK CARDIO	06-02-2012

107745AB	PACK PACING TEMP. S.JOAO	06-02-2012
104587AG	KANTONSSPITAL ST.GALLEN,RADIOLOGIE	09-02-2012
106942AE	LIESTAL CORO-SET	13-02-2012
105657AB	PACK PACEMAKER	13-02-2012
107122AE	CVC SET	20-02-2012
100676AB	ANGIOTRAY	23-02-2012
107876AA	ANGIODYN SET	05-03-2012
107769AA	POETSSET CVC	08-03-2012
107359AC	PACEMAKERSET	13-03-2012
100911AN	HEUP PAKKET	22-03-2012
100926AN	KNIE/SCHOUDER PAKKET	22-03-2012
106918AD	EVAR TRAY	22-03-2012
107745AD	IMH ANGIO PROCEDURE PACK	29-03-2012
05004	CIRCUMCISION SET	03-04-2012
105314AH	VAAT TRAY	12-04-2012
102887AD	CATHETER PACK	17-04-2012
108162AA	1 KLINIKI WROCLAW	07-05-2012
102095AI	TRAY MAMMA	07-05-2012
106245AD	VNUS TRAY	10-05-2012
106496AE	PACEMAKER	10-05-2012
102808AE	PACK CARDIO	29-05-2012
105798AB	ANGIO PACK	07-06-2012
105657AC	PACK PACEMAKER	18-06-2012
101855AH	PACK ANGIO/HEMODINAMICA	27-06-2012
108254AB	OOGLEDEN SET	27-06-2012
107769AB	POETSSET CVC	27-06-2012
105314AI	VAAT TRAY	28-06-2012
107766AE	PREMIUM D-1	05-07-2012
100903AJ	LAPAROSCOPIE PAKKET	09-07-2012
100905AJ	VSM PAKKET	09-07-2012
100906AK	LIESBREUK PAKKET	09-07-2012
100912AJ	SCHOUDER KLEIN PAKKET	09-07-2012
100915AK	SHUNT PAKKET	09-07-2012
100911AO	HEUP PAKKET	09-07-2012
100926AO	KNIE/SCHOUDER PAKKET	09-07-2012
103080AH	VOET PAKKET	09-07-2012
100901AM	SECTIO PAKKET	09-07-2012
107229AB	CVC TRAY ICU	12-07-2012
101992AK	HEUP COMPLEET TRAY	12-07-2012
102867AL	TOTALE HEUP TRAY	12-07-2012
108254AC	OOGLEDEN SET	17-07-2012
105848AJ	TRAY TOTALE KNIE	23-07-2012
107086AC	TOTALE KNIE TRAY	23-07-2012
107087AE	TOTALE HEUP TRAY	23-07-2012
106815AE	EVAR TRAY	26-07-2012
100926AP	KNIE/SCHOUDER PAKKET	26-07-2012
108089AB	TRAY TEPP PAKKET 1	07-08-2012
106500AI	GROTE PROCEDURE TRAY	07-08-2012
106503AH	VAAT TRAY	07-08-2012
106507AH	HEUP TRAY	07-08-2012
106519AH	TOTALE KNIE	07-08-2012
106510AE	SECTIO TRAY	07-08-2012
106526AF	NEURO TRAY	07-08-2012
106543AF	OPEN SCHOUDER TRAY	09-08-2012
107583AB	EXTENSIE TRAY	09-08-2012

106516AG	MAMMA TRAY	09-08-2012
106942AF	LIESTAL CORO-SET	16-08-2012
108331AA	HNP TRAY	20-08-2012
102429AE	PACK HARTCATHETERISATIE	04-09-2012
103715AG	TRAY HEUP	11-09-2012
108192AC	HEUP PAKKET MEDICA	13-09-2012
108200AC	KNIE/SCHOUDER PAKKET MEDICA	13-09-2012
103297AH	SECTIO TRAY	17-09-2012
108362AA	BA-X8513	16-10-2012
108364AA	BA-X 8506	16-10-2012
105657AD	PACK PACEMAKER	29-10-2012
107086AD	TOTALE KNIE TRAY	08-11-2012
107087AF	TOTALE HEUP TRAY	08-11-2012
102043AI	ARTHROSCOPIE TRAY	21-11-2012
106510AF	SECTIO TRAY	23-11-2012
102808AF	PACK CARDIO	26-11-2012
104587AH	KANTONSPITAL ST.GALLEN,RADIOLOGIE	26-11-2012
106679AE	VNUS TRAY	14-12-2012
103860AI	POLI EXTREMITETEN TRAY	03-01-2013
103861AH	OOGLEDEN TRAY	03-01-2013
102198AE	BY PASS PACK, TRENTO	07-01-2013
103463AJ	VASECTOMIE PAKKET	07-01-2013
104611AP	ROBOT TRAY	07-01-2013
102198AE	BY PASS PACK, TRENTO	09-01-2013
103967AJ	GROOT BASIS TRAY EURO	18-01-2013
103981AH	VARICES TRAY EURO	18-01-2013
103983AH	SECTIO TRAY	18-01-2013
102095AL	TRAY MAMMA	29-01-2013
108591AC	OOR TRAY	04-02-2013
105848AK	TOTALE KNIE TRAY	05-02-2013
108089AC	TRAY TEPP PAKKET 1	14-02-2013
108723AA	PACK CAT.VEN CENTRAL	18-02-2013
108733AB	SG ANGIO PROCEDURE PACK	01-03-2013
108683AB	OPEN HEART KIT	12-03-2013
108684AB	ANGIO KIT	02-04-2013
109010AA	CVC INBRENGSET	04-04-2013
102831AJ	ANGIOGRAFIESET	12-04-2013
102095AM	MAMMA TRAY	12-04-2013
103989AI	EXTENSIE TRAY	16-04-2013
101190AQ	TOTALE KNIEPROTHESE TRAY	16-04-2013
101189AQ	TOTALE HEUPPROTHESE TRAY	16-04-2013
109072AA	HIP SET	23-04-2013
109074AA	CVC SET	25-04-2013
106506AF	VKB TRAY	25-04-2013
109026AA	PERICARDINAL TAP SET	02-05-2013
102867AM	TOTALE HEUP TRAY	30-05-2013
108200AE	KNIE/SCHOUDER PAKKET	19-06-2013
108192AE	HEUP PAKKET	19-06-2013
109253AB	CVC TRIPLE LUMEN AH 15703	20-06-2013
108667AC	SCHOUDERSCOPIE TRAY	04-07-2013
109377AA	SCHOUDERPROTHESE TRAY	04-07-2013
108671AC	SECTIO TRAY EUROGUARD	04-07-2013
108888AB	ENDOSCOPISCHE DARMCHIRGI	04-07-2013
109376AA	HEUPPROTHESE VOORSTE BEN.	04-07-2013
108672AC	TANDETRACTIE TRAY	04-07-2013

108641AB	VAGINALE PLASTIEKEN TRAY	04-07-2013
108645AC	OORTRAY EUROGUARD	04-07-2013
108643AB	LAVH TRAY EUROGUARD	04-07-2013
108649AC	NEUS TRAY EUROGUARD	04-07-2013
108660AC	ENDO ADNEX TRAY	04-07-2013
108733AC	SG ANGIO PROCEDURE PACK	04-07-2013
100915AL	SHUNT PAKKET	09-07-2013
109377AB	SCHOUDERPROTHESE TRAY	17-07-2013
108187AC	CARDIO PACK	30-07-2013
109610AA	ANGIOPACK	01-08-2013
109659AA	SG ANGIO PROCEDURE PACK VERSION 2	01-08-2013
108733AE	SG ANGIO PROCEDURE PACK	01-08-2013
107369AC	PACEMAKER TRAY	27-08-2013
109680AA	SG ANGIO PACK	28-08-2013
109243AB	CVC TRIPLE LUMEN AH	13-09-2013
103527AD	PACK CARDIO	30-09-2013
102808AH	PACK CARDIO	07-10-2013
103297AK	SECTIO TRAY	07-10-2013
106518AJ	VUE TRAY	14-10-2013
106543AG	OPEN SCHOUDER TRAY	14-10-2013
106516AH	MAMMA TRAY	14-10-2013
106510AG	SECTIO TRAY	14-10-2013
107583AC	EXTENSIE TRAY	14-10-2013
106506AH	VKB TRAY	14-10-2013
106500AK	GROTE PROCEDURE TRAY	14-10-2013
106526AG	NEURO TRAY	14-10-2013
106519AJ	TOTALE KNIE TRAY	16-10-2013
106507AJ	HEUP TRAY	16-10-2013
108960AB	PACK CARDIO CURACAO	07-11-2013
108649AF	NEUS TRAY EUROGUARD	07-11-2013
109756AB	CAPAROSCOPIE TRAY KLEIN	07-11-2013
108667AD	SCHOUDERSCOPIE TRAY EUROGUARD	07-11-2013
108672AE	TRANDEXTRACTIE TRAY EUROGUARD	07-11-2013
108660AD	ENDO ADNEX TRAY EUROGUARD	07-11-2013
105016AE	TEP TRAY	07-11-2013
105009AI	GASTRIC BYPASS/SLEEVE TRAY	07-11-2013
108643AC	LAVH TRAY EUROGUARD	07-11-2013
106942AG	LIESTAL CORO-SET	07-11-2013
107087AH	TOTALE HEUP TRAY	07-11-2013
107086AE	TOTALE KNIE TRAY	07-11-2013
108888AC	ENDOSCOPISCHE DARMCHIRGI	07-11-2013
108671AD	SECTIO TRAY EUROGUARD	07-11-2013
108960AC	PACK CARDIO CURACAO	12-11-2013
106679AF	VNUS TRAY	12-11-2013
108868AB	STRABISMUS PAKKET	22-11-2013
101855AI	PACK ANGIO/HEMODINAMICA	22-11-2013
109376AB	HEUPPROTHESE VOORSTE BEN.	09-12-2013
106503AJ	VAAT TRAY	16-12-2013
108845AB	ANGIO CARDIO PACK	23-12-2013
108846AB	ANGIO RADIO PACK	23-12-2013
109749AB	ZUIGDRAINAGE SET	23-12-2013
109884AC	CAROTIS TRAY	21-01-2014
109371AC	MAMMA TRAY	03-02-2014
101914AG	TRAY PACEMAKER	05-02-2014
100915AM	SHUNT PAKKET	05-02-2014

109756AC	LAPAROSCOPIE TRAY KLEIN	06-02-2014
110159AB	HEUP ZIJLIGGING	17-02-2014
100901AN	SECTIO PAKKET	17-02-2014
108660AE	ENDO ADNEX TRAY EUROGUARD	03-03-2014
108643AD	LAVH TRAY EUROGUARD	03-03-2014
108888AD	ENDOSCOPISCHE DARMCHIRGIE	03-03-2014
109610AC	ANGIOPACK	05-03-2014
101914AH	TRAY PACEMAKER	17-03-2014
102492AF	HCK PACK	17-03-2014
100901AO	SECTIO PAKKET	26-03-2014
100903AK	LAPAROSCOPIE PAKKET	26-03-2014
100905AK	VSM PAKKET	26-03-2014
100906AL	LIESBREUK PAKKET	26-03-2014
100915AN	SHUNT PAKKET	26-03-2014
103080AI	VOET PAKKET	26-03-2014
103983AI	SECTIO TRAY	26-03-2014
108200AF	KNIE/SCHOUDER PAKKET	26-03-2014
109375AD	LD TRAY	26-03-2014
110159AB	HEUP ZIJLIGGING	26-03-2014
100912AL	SCHOUDER KLEIN PAKKET	31-03-2014
108192AF	HEUP PAKKET	31-03-2014
103297AL	SECTIO TRAY	07-04-2014
101992AL	HEUP COMPLEET TRAY	16-04-2014
102867AN	TOTALE HEUP TRAY	16-04-2014
105848AL	TOTALE KNIE TRAY	16-04-2014
108331AB	HNP TRAY	16-04-2014
108672AF	TANDETRACTIE TRAY EUROGUARD	16-04-2014
109749AC	ZUIGDRAINAGE SET	16-04-2014
109371AD	MAMMA TRAY AVL-NKI	24-04-2014
110290AA	ANGIO PACK 2	28-04-2014
110383AA	ANGIO SET	28-04-2014
105798AD	ANGIO PACK	30-04-2014
106679AH	VNUS TRAY	28-05-2014
108671AE	SECTIO TRAY EUROGUARD	16-06-2014
108683AG	OPEN HEART KIT	25-06-2014
109664AC	CVC LIJNEN SET	25-06-2014
109883AB	VARICES TRAY	25-06-2014
103989AJ	EXTENSIE TRAY	16-07-2014
108869AA	SCHILDKLIER TRAY	16-07-2014
110411AB	CVC SET TRIPLE LUMEN EUROGUARD	16-07-2014
110412AB	CVC SET DUBBEL LUMEN EUROGUARD	16-07-2014
100901AP	SECTIO PAKKET	17-07-2014
100903AL	LAPAROSCOPIE PAKKET	17-07-2014
100905AL	VSM PAKKET	17-07-2014
100915AO	SHUNT PAKKET	17-07-2014
108868AC	STRABISMUS PAKKET	17-07-2014
102997AF	TREPANATIESET ME	23-07-2014
103983AJ	SECTIO TRAY	23-07-2014
102887AH	CATHETER PACK	27-08-2014
109610AD	ANGIOPACK	25-08-2014
100906AN	LIESBREUK PAKKET	10-09-2014
101438AK	CRANIOTOMIEPAKKET	10-09-2014