

Memo

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 Date : July 06th, 2021

Title : Integrating EC9-4 and 10MC3 on Transducer Family Classification for Reprocessing (P/N 11508925).

■ Executive Summary:

This report describes that material compatibility is related to the type of materials rather than the manufacturer. Therefore, 10MC3 and EC9-4 could be integrated into the same group on Transducer Family Classification for Reprocessing (P/N 11508925).

Transducers are grouped per outer material composition and construction based on the Transducer Family Classification for Reprocessing (P/N 11508925).

All outer materials of both 10MC3 and EC9-4 are of the same. But both transducers were divided into different groups because the manufacturers of the lens material were different. However, from chemical properties and testing result, it was verified that material compatibility is related to type of materials, not to manufacturer.

Therefore, it is considered that 10MC3 and EC9-4 could be integrated into the same group.

■ AS-IS & TO-BE

< AS-IS >

Family	Transducer	PN
E1	10MC3	11284842 & 11268679
E2	EC9-4	8648029/ 10789383 & 10136144

< TO-BE >

Family	Transducer	PN
E1	10MC3	11284842 & 11268679
	EC9-4	8648029/ 10789383 & 10136144

■ Outer Material

The manufacturers are different, but type of lens materials are the same.

Transducer	Lens		
	Manufacturer	Type	Name
10MC3	Dow Corning	RTV Silicone	Q5-8008
EC9-4	GE Silicones	RTV Silicone	RTV 664

■ Analysis








● Lens material




The table below is the material composition of Q5-8008 and RTV664 part A. Both lens materials have same molecular structure called PDMS. Even though the molecular back bone is same, the CAS numbers ;68083-19-2 and 68584-83-8; differ based on extra functional groups in polymeric chains. Therefore, they will be the same type of RTV silicone once they get cured. Moreover, both lens materials will exhibit similar properties and will have similar material compatibility.

Transducer	Polymer material	CAS	Concentration
Q5-8008	VINYL TERMINATED POLYDIMETHYLSILOXANE	68083-19-2	40-70
RTV664 part A	VINYL TERMINATED POLYDIMETHYLSILOXANE	68083-19-2	30-60
	VINYL containing resin	68584-83-8	10-30

● Material compatibility test results

To confirm the similarity of material compatibility of EC9-4 and 10MC3, the actual test results were compared. As a result, it is verified that both transducers have same test results. So, it is considered that if the type of materials is same, the material compatibility test results are also same.

Disinfectant	Active ingredient	Transducer	Test Result	Report
Tropon EPR	Hydrogen Peroxide (34.9-37.0%)	10MC3	Compatible	 Report_Griffin_Tro phon compatibility
		EC9-4	Compatible	 01. Technical report_Evaluation \
Antigermix AS1	UV	10MC3	Compatible	 Technical report_Materials cc
		EC9-4	Compatible	 Technical report_Materials cc
Cidex OPA	Ortho-phthalaldehyde (0.55%)	10MC3	Compatible	 Tech Report_10MC3 Dis
Cidex Plus	Glutaraldehyde (3.4%)	EC9-4	Compatible	 EC9-4(STI)_high-le vel disinfectant.pdf
Gigasept FF	Succindialdehyde (11.9%), Dimethoxytetrahydrofuran(3.2%)			 EC9-4(TSB)_high-l evel disinfectant.p

Perform	Pentapotassium bis(peroxymonosulphate) bis(sulphate) (45%)	10MC3	Compatible	 Technical report_Materials cc
	Anionic surfactants (5-15%) Non-ionic surfactants (<5%)	EC9-4	Compatible	
Anioxide 1000LD	Peracetic acid (0.09-0.15%)	10MC3	Compatible	 DCM11_Technical report_Materials cc
		EC9-4	Compatible	
Clinell Universal Wipes	Quat + Biguanide	10MC3	Compatible	 Technical Report_compatibili
		EC9-4	Compatible	

■ Conclusion

It is verified that material compatibility is related to the type of RTV silicone rather than the manufacturer. Therefore, 10MC3 and EC9-4 could be integrated into the same group on Transducer Family Classification for Reprocessing (P/N 11508925).

10MC3 will be a representative. Please refer to the Transducer Family Classification for Reprocessing (P/N 11508925) for more detail. Therefore, EC9-4 can be covered by the test result of 10MC3. This result will be updated in Transducer Disinfectant Compatibility Matrix (P/N 11335653).

■ Compatibility results

1. HLD

Transducer Pricebook P/N1 or Transducer Material P/N	Transducer MODEL	Transducer Manufacturer	Alkacide	WipeClean Chlorine Disinfection
11268679	10MC3	Siemens	C	C
11284842	10MC3	Siemens	C	C
8648029/ 10030334/ 10789383	EC9-4	Siemens	C	C
10136144/ 11015394	EC9-4	Siemens	C	C

3. Pre-Cleaners

10136144/ 11015394	EC9-4	Siemens	Transducer Pricebook P/N ¹ or Transducer Material P/N
			Transducer MODEL
			Transducer Manufacturer
			Alkazyme
			Clinell Clorox Wipes
			Clorox Healthcare Bleach Germicidal Wipes
			Clorox Healthcare Fuzion Cleaner Disinfectant
			Dispatch
			Micro-Kill Bleach Germicidal Bleach Wipes
			Sani-Cloth Bleach Germicidal Disposable Wipes
			Sani-Cloth Chlor Wipes
			Sekulyse
			Sekusept Extra N

[illegible]



- ✓ For some disinfectants, 10MC3 is covered by testing results of EC9-4. Because all transducers applied with Q5-8008 are compatible, it is considered that 10mc3 would have the same result. Please refer to the appendix 2 for more information.

■ REFERENCES:

Document Description	P/N
[1] Transducer Disinfectant Compatibility Matrix	P/N 11335653
[2] Transducer Family Classification for Reprocessing	P/N 11508925

■ APPENDIX:

1. SDS

1) Q5-8008



86_Q5-8008(Base
&Curing).pdf








2) RTV664



RTV 664_part
A_MSDS.pdf



RTV 664_part
B_MSDS.pdf

Disinfectant	Test report
WipeClean Chlorine Disinfection	 Memo_Sani Cloth Chlor, Wipe Clean
Sani-Cloth Chlor Wipes	
Clorox Healthcare Fuzion Cleaner Disinfectant	
Dispatch	 Memo_Validation of Dispatch.pdf
Micro-Kill Bleach Germicidal Bleach Wipes	 Memo for new disinfectants & Cle
Sani-Cloth Bleach Germicidal Disposable Wipes	 Memo_Sani-Cloth Bleach Germicidal
Clinell Clorox Wipes	 Memo_Compatibil ity_Clinell Clorox w
Clorox Healthcare Bleach Germicidal Wipes	 Clorox Bleach Germicidal Cleani
Alkazyme	 Acouson Lens material _ Disinfec
HEXANIOS G+ R	