shellty

CERTIFICATION MANUAL

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About IHCare - Innovation Hospital Care

IHCare is certified by the National Innovation Agency (ANI) with suitability recognition in the areas of research and development within the healthcare domain. (*see Attachments*) The company is driven by three fundamental principles: research, development, and implementation of technological solutions, with an emphasis on saving resources for the maximization of time and money of health units.

Our mission is to significantly improve patient comfort and well-being by providing effective means to combat cross-infection with overall clinical, human, and financial improvements.

With this in mind, we came up with an innovative bedsheet, Shellty, that is placed over the mattress and can substitute the mattress cover, mattress protector, and bottom sheet. This manual is a compilation of all the certifications that Shellty has, as well as a summarized analysis of the results that allowed our certification partners to grant us certification.

Shellty

Main Characteristics

Shellty Bedding is a high-tech textile lining with a 100% polyester (PES) interlock composition. Its hydrophobic, biocompatible, antiviral, and antibacterial characteristics allow for a highly impermeable and breathable material that aims to replace the conventional sheets used in the care of bedridden patients, reducing the time and effort spent in the care of these patients.

Supply chain

Coltec is responsible for the production of the textile lining and the interior membrane that composes the Shellty products, and also for the impregnation of the textile with the repellent and anti-bacterial solution. The following data constitute Shellty's technical chart, provided by Coltec, regarding the mesh used for the textile lining.

As stated before, the textile lining is made out of a membrane composed of a thermoplastic polyurethane resin film, about 20 µm thick and white, with the following properties:

Performance Properties			
Properties	Método	Units	Values
Water column	EN ISO 20811	m	>10
Melting point	ISO 11357	ºC	≈175ºC
Density	DIN 53243	g/mm3	≈1,26

Coltec is also responsible for the production of the textile substrate in the loom. This textile is completely made of polyester, with an interlock structure, weighing about 130g/m^2 , 1,60m wide, and white. Once the textile lining is made, it is then impregnated with 2 different solutions, made by Rudolf Chemicals, one is responsible for the water-repellent finishing while the other is responsible for the bioactive properties.

Once this process is complete, the membrane and the textile substrate are laminated together forming a textile lining with all the characteristics described above.
This lining is then sent to Scoop, who is responsible for transforming the textile into individual, finished products like pillowcases and sheets in various sizes.

Certifications

Our certification partners, *Equilibrium* and *CITEVE*, have thoroughly tested the characteristics described above in their laboratories.
Both labs will renew these tests every 6 months to ensure all characteristics remain unaltered, and our product maintains its high performance. Both labs have also presented their results with an expanded uncertainty that was calculated by multiplying the padron uncertainty by the expansion factor (K=2), which gives the results a trust level of 95%.

Citeve - Wash resistance assays

CITEVE, the lab department of the Portuguese Centre for the Textile and Clothing Industries, tested Shellty Bedding using a provided sample of our product, according to the requirements of EN 13795-1 and EN 13795-2 (Medical Devices norm), resulting in the following results (pertaining to the period of March - June 2023).

If you prefer to see the official report forwarded by CITEVE to IHCare, you can do so in the *Attachment*s.

The sample provided was divided into 3 sections: sample 1763/2023 was kept in its original state and tested as thus; sample 3077/2023 was tested after being put through 70 industrial wash cycles; and finally, sample 3078/2023 was tested after going through 70 domestic wash cycles.

Below you can find the results (per assay per sample) of each assay:

➔ **EN ISO 9073-10:2004 - Dry release of particles**:
The particle release coefficient never exceeded the maximum value requirement of 4,0, for any of the samples. The samples that had gone through wash cycles had an even smaller coefficient when compared to the original sample. The results indicate that all samples comply with the requirements for EN 13795-1/2:2019, regarding norm ISO 9073-10:2004.

ESSAY GROUP REQUESTED: **EN 13795-1/2:2019**	LIBERTAÇÃO DE PARTÍCULAS A SECO **EN ISO 9073-10:2004**

		Particle release coefficient					
Sample Number	Reference	Max	Min	Median	Upper quartile	Requirement value	
1763/2023	001	3,8	3,0	3,4	3,6	max 4,0	(Results after wash)
3077/2023	001	3,0	2,1	2,8	2,9		
3078 /2023	001	1,6	0,9	1,2	1,4		

Essay characteristics		
Particle Counter Technology	Particle Size	Relative expanded uncertainty (K=2)
diode laser (spherical)	3 a 25µ	16%

➔ **EN ISO 811:2018 - Resistance to water penetration:**
The resistance value was always higher than 100 cm H_2O for all samples regardless of washing cycles, for all 5 tests performed on each sample. These results meet all requirements of EN 13795-1/2:2019, regarding norm ISO 811:2018, for both scrubs and protective equipment, standard and high performance, and different critical areas.

ESSAY GROUP REQUESTED: **EN 13795-1/2:2019**	RESISTÊNCIA À PENETRAÇÃO DE ÁGUA **EN ISO 811:2018**

		Resistance values (cm H2O)				
Sample Number	Reference	Individual value	Median	Lower quartile	Requirement value	
1763/2023	001	>100 [1]	---	---	(See table to the right)	(Results after wash)
3077/2023	001	>100	>100	>100		
3078 /2023	001	>100	>100	>100		

Table of requirements								
Scrubs				Protective equipment				Relative expanded uncertainty (K=2)
Normal performance		High performance		Normal performance		High performance		
Critical area	Less critical area	Critical area	Less critical area	Critical area	Less critical area	Critical area	Less critical area	
miin 20 cm H2O	min 10 cm H2O	min 100 cm H2O	min 10 cm H2O	min 30 cm H2O	min 10 cm H2O	min 100 cm H2O	min 10 cm H2O	19%

Essay Conditions					
Nº tested cylinder	Water temperature (ºC)	Water pressure	Face tested	Pressure increase velocity	Condicioned environment
5	20ºC	Under the cylinder	Right side	10 cm H2O/min	20+/-2ºC & 65+/-4% H.R.

➔ **EN ISO 13938-1:2019 - Bursting resistance when dry:**

For this norm, the minimum requirement value of the bursting force is 40 kPa. All samples, regardless of the washing procedure, achieved a value well over the minimum. In fact, in all trials, for all 3 samples, this value was over 90 kPa, easily meeting the requirements of EN 13795-1/2:2019.

ESSAY GROUP REQUESTED: **EN 13795-1/2:2019**	RESISTÊNCIA AO REBENTAMENTO - SECO **EN ISO 13938-1:2019**

		Bursting force (kPa)					
Sample Number	Reference	Max	Min	Median	Lower quartile	Requirement value	
1763/2023	001	226	117	138	124	min 40 kPa	(Results after wash)
3077/2023	001	123	90,7	101	97,5		
3078 /2023	001	125	116	123	123		

NOTE: THESE ESSAYS WERE CONDUCTED WITH THE MEMBRANE FACING UPWARDS

Essay Conditions				Essay Characteristics
Conditioned cylinder	N° tested cylinder	Tested area (cm2)	Equipment	Relative expanded uncertainty (K=2)
Dry	5	7,3 cm2	Autoburst M229	15%

➔ **EN ISO 13938-1:2019 - Bursting resistance when wet:**

In this assay, the minimum requirement value of the bursting force is the same as the last one (40 kPa). Once again, all samples scored higher bursting force values than required. However, these values were overall lower than their dry test counterparts, which was even more noticeable in the previously washed samples. Even so, all values were over 50 kPa meeting the requirements for EN 13795-1/2:2019 regarding EN ISO 13938-1:2019.

ESSAY GROUP REQUESTED: **EN 13795-1/2:2019**	RESISTÊNCIA AO REBENTAMENTO - MOLHADO **EN ISO 13938-1:2019**

		Bursting force (kPa)					
Sample Number	Reference	Max	Min	Median	Lower quartile	Requirement value	
1763/2023	001	113	82,2	95,8	95,8	min 40 kPa	(Results after wash)
3077/2023	001	86,2	70,2	76,6	70,2		
3078 /2023	001	93,7	51,1	75,1	65,5		

NOTE: THESE ESSAYS WERE CONDUCTED WITH THE MEMBRANE FACING UPWARDS

Essay conditions							Essay Characteristics
onditioned cylind	Steeping Conditions			N° tested cylinder	Tested area (cm2)	Equipment	Relative expanded uncertainty (K=2)
	mmersion solutio	ater temperature (°C	Immersion time (h)				
Wet	ter & 1g/L non-ic	20°C	1h	5	7,3 cm2	Autoburst M229	15%

➔ **EN 29073-3:1992 - Resistance to rupture and elongation when dry:**

For this norm, there are specific strength requirements for either scrubs or protective equipment, both having between 15N and 20N as a minimum requirement in all instances. The samples' resistance was tested both longitudinally and transversally, achieving values over 300N for all samples in both directions, ensuring that the requirements for EN 13795-1/2:2019 are met where it concerns norm EN 29073-3:1992.

ESSAY GROUP REQUESTED: EN 13795-1/2:2019	RESISTÊNCIA À ROTURA E ALONGAMENTO - SECO EN 29073-3:1992

		Strength (N)									
		Longitudinal				Transversal				Requirement value	
Sample Number	Reference	Max	Min	Median	Lower quartile	Max	Min	Median	Lower quartile		
1763/2023	001	773	646	677	654	380	348	367	349	(See table to the right)	(Results after wash)
3077/2023	001	742	681	701	696	382	331	351	345		
3078 /2023	001	569	433	511	482	371	302	330	327		

Note: for samples 3077/2023 and 3078/2023 the graduated cylinder broke next to the mouth in both directions

Table of requirements			
Scrubs	Protective Equipment		e expanded uncertainty
	ormal performan	high performance	
min 20 N	min 15 N	min 20 N	13%

Essay conditions	
Conditioned cylinder	Conditioned environment
Dry	20+/-2ºC e 65+/-4% H.R.

➔ **EN 29073-3:1992 - Resistance to rupture and elongation when wet:**

The wet test for norm EN 29073-3:1992 had the same requirements as the dry test (between 15N and 20N). In this assay the samples were also tested longitudinally and transversally, achieving in all 3 cases values over 300N regardless of direction. As such, concerning assay EN 29073-3:1992, the requirements were once again met for EN 13795-1/2:2019.

ESSAY GROUP REQUESTED: EN 13795-1/2:2019	RESISTÊNCIA À ROTURA E ALONGAMENTO - MOLHADO EN 29073-3:1992

		Strength (N)									
		Longitudinal				Transversal				Requirement value	
Sample Number	Reference	Max	Min	Median	Bottom quartile	Max	Min	Median	Bottom quartile		
1763/2023	001	747	688	719	711	378	339	364	348	(See table below)	(Results after wash)
3077/2023	001	770	650	700	690	400	360	370	370		
3078 /2023	001	726	611	703	673	307	374	330	329		

Note: for samples 3077/2023 and 3078/2023 the graduated cylinder broke next to the mouth in both directions

Table of requirements			
Scrubs	Protective Equipment		Relative expanded uncertainty (K=2)
	Normal performance	High performance	
min 20 N	min 15 N	min 20 N	11%

Essay conditions				
Conditioned beaker	Steeping Conditions			Conditioned environment
	Immersion solution	Water temperature (ºC)	Immersion time (h)	
Wet	Grade 3 water & 1g/L non-ionic steeper	20ºC	1h	20+/-2oC e 65+/-4% H.R.

➔ **ISO 22610: 2006 - Resistance to bacterial penetration when wet:**

This assay was only conducted for the sample in its original state. The barrier index for this assay is considered standard when it's over or equal to 2,8 and high performance when it's 6,0. The lowest index value of all trials was 5,3, with an average of 5,9, showing an incredibly high standard value, meeting the requirements of EN 13795-1:2019, regarding ISO 22610: 2006.

ESSAY GROUP REQUESTED: **EN 13795-1/2:2019**	RESISTÊNCIA A PENETRAÇÃO BACTERIANA A HÚMIDO **ISO 22610 : 2006**

Note. this essay was only conducted for sample 1763/2023

Essay Conditions (EN 13795-1:2019)		
Barrier index	Standard performance	>/= 2,8
	High performance	6,0

Staphylococcus aureus (ATCC 29213)	
Innoculum Conc. (UFC/mL)	10 000 a 40 000
Transference membrane	PU membrane with 30 µm diameter
Nº tested samples	5
Sample size (cm)	25 x 25
Distance from agar to hedge of plate (mm)	3 +/- 0,2
Temperature (ºC)	22ºC
Relative humidity (%)	41%

Performance monitoring:
Graphite paper - presence of padron throughout the plate
Reference material (CUM5 0,7 - 0,96)

	Colony count (per replica, per trial) (CFU)					
Sample tested	X1	X2	X3	X4	X5	Z
Trial 1	7	7	6	0	3	654
Trial 2	5	3	2	2	4	769
Trial 3	46	48	54	56	50	877
Trial 4	9	8	10	3	1	970
Trial 5	19	10	4	7	7	950

	Barrier index		Expanded uncertainty (K=2)
Sample tested	Per replica	Average value	
Trial 1	5,9		
Trial 2	5,9		
Trial 3	5,3	5,9	1,0
Trial 4	5,9		
Trial 5	5,8		

➔ **ISO 22612:2005 - Resistance to bacterial penetration when dry**

This assay was also only conducted for the original sample. The requirements for this norm are different for EN 13795-1:2019 and EN 13795-2:2019. For EN 13795-1:2019, the upper quartile should have 300 CFU or less; for EN 13795-2:2019, the upper quartile should be 100 CFU or less for a standard performance and 50 CFU or less for a high performance. In our trials, the colony units in the upper quartile were 1 CFU. As such, our sample meets the requirements of both EN 13795-1:2019 and EN 13795-2:2019.

ESSAY GROUP REQUESTED: **EN 13795-1/2:2019**	RESISTÊNCIA A PENETRAÇÃO BACTERIANA A SECO **ISO 22612:2005**

Note. this essay was only conducted for sample 1763/2023

Bacillus subtilis spores (ATCC 9372)	
Talc conc. (CFU/g)	10^8
Side exposed to inoculum giver	Interior
Graduated cylinders tested	10
Average mass of contaminated talc per cylinder (g)	0,5+/-0,1
Graduated cylinder size	200 x 200
Graduated cylinder sterilization method	N/A
Vibration time (min)	30
Vibration frequency (vib/min)	20 800
Relative humidity (%)	65 +/- 5 %
Temperature (ºC)	20 +/- 2 ºC

Essay conditions		
EN 13795-1:2019		Uq </= 300 CFU
EN 13795-2:2019	Standart performance	Uq </= 100 CFU
	High performance	Uq </= 50 CFU

			Colony units			
Cylinder tested	Individual values (CFU)		Average (CFU)	Median (Md) (CFU)	Upper quartile (Uq) (CFU)	Expanded uncertainty (K=2)
1º/ 7º	1	0				
2º/ 8º	1	1				
3º/ 9º	1	0	1	1	1	7
4º/ 10º	0	1				
5º/ 11º	1	2				
6º/ 12º	0	0				Control group

➔ **ISO 11737-1:2018 (EN 13795) - Microbiologic control (Bioburden):**
This assay was also performed only for the sample without wash cycles. Similarly to the previous one, the minimal requirements for the norm are divided between EN 13795-1:2019 and EN 13795-2:2019. For EN 13795-1:2019 the upper quartile must have a maximum of 300 CFU/ 100 cm^2 and for EN 13795-2:2019 the upper quartile must have a maximum of 100 CFU/ 100 cm^2. Our sample scored a total of 92 CFU/ 100cm^2 in its upper quartile, meeting the requirements for both assays (EN 13795-1:2019 and EN 13795-2:2019).

ESSAY GROUP REQUESTED: **EN 13795-1/2:2019**	CONTROLO MICROBIOLÓGICO (BIOBURDEN) **ISO 11737-1:2018 (EN 13795)**

Note. this essay was only conducted for sample 1763/2023

	Total removed microorganisms (CFU/ 100cm2)				Minimall requirements for upper quartile	
Essay number	Individual value	Median value	Upper quartile	Expanded Uncertainty (K=2)	EN 13795-1: 2019	EN 13795-2: 2019
1º Trial	50	52	92	4	max 300 CFU/100 cm2	max 100 CFU/100 cm2
2º Trial	52					
3º Trial	106					
4º Trial	92					
5º Trial	52					

➔ **EN ISO 15797:2018 - Previous treatment - industrial wash and finishing:**
EN ISO 15797:2018 was only performed for sample 3077/2023, the sample representing 70 cycles of industrial washes. The norm merely describes the washing and finishing procedure of industrial wash cycles.

ESSAY GROUP REQUESTED: **EN 13795-1/2:2019**	TRATAMENTO PRÉVIO - LAVAGEM E ACABAMENTO INDUSTRIA **EN ISO 15797:2018**

Note. this essay was only conducted for sample 3077/2023

Essay conditions	
Washing machine	Electrolux W4240H
Washing program	Table 1, reduced load, 30ºC
Total load (kg)	13
Detergent used	Name-brand reference detergent without whitener
Drying method	A - tumble dryer
Dryer	Electrolux T5675
Number of washing/drying cyles	70
Drying temperature	60/70ºC

➔ **ISO 6330:2012 - Previous treatment - domestic wash**

Similarly to EN ISO 15797:2018, this norm (ISO 6330:2012) was only applied to sample 3078/2023, which represents our product after 70 domestic wash cycles.

ESSAY GROUP REQUESTED: **EN 13795-1/2:2019**	TRATAMENTO PRÉVIO - LAVAGEM DOMÉSTICA **ISO 6330:2012**

Note. this essay was only conducted for sample 3078/2023

Essay conditions	
Washing machine	Type A
Washing program	3N (30ºC)
Total load (Kg)	2
Detergent used	ECE + TAED + sodium perborate
Dryer	James H. Heal Modelo Accudry
Drying process	Tumble dryer (normal temp.)
Number of washing/drying cycles	70
Drying temperature	60/70ºC

➔ **ISO 4920:2012 - Resistance to surface wetting (Shower test)**

This assay was only conducted for the samples that had been previously washed (3077/2023 and 3078/2023). Sample 3077/2023 was ironed at 150ºC before this assay. Both samples had the same assay conditions; and got a 5 on the classification scale of ISO 4920, which is the highest possible classification and means the samples had no water adherence to their surface. EN 13795-1:2019 and EN 13795-2:2019 have no requirements for this assay.

ESSAY GROUP REQUESTED: **EN 13795-1/2:2019**	RESISTÊNCIA À MOLHAGEM SUPERFICIAL (ENSAIO DO CHUVEIRO) **ISO 4920:2012**

Note. this essay was only conducted for samples 3077/2023 and 3078/2023

Note: for sample 3077/2023 this essay was conducted after performing essay EN ISO 15797:2018 (washing) and ironing the sample at 150ºC

Essay conditions for sample 3077/2023	
Water temperature (ºC)	Conditioned environment
20±2ºC	20+/-2ºC e 65+/-4% H.R.

Results after washing (*see EN ISO 15797:2018*)	
Individual values	ISO 5
	ISO 5
	ISO 5

Note: for sample 3078/2023 this essay was conducted after performing essay EN ISO 6330:2012 (washing)

Essay conditions for sample 3078/2023	
Water temperature (ºC)	Conditioned environment
20±2ºC	20+/-2ºC e 65+/-4% H.R

Results after washing (*see EN ISO 6330:2012*)	
Individual values	ISO 5
	ISO 5
	ISO 5

Como interpretar este teste?
Relativamente ao spray test (ISO 4920) segundo a escala de classificação obteve um 5, isto significa que quando a amostra foi submetida a ensaio a mesma não "molhou" nem aderiu água à superfície.

➔ **AATCC TM79-2010e2(2018)e - Hidrophilicity of whitened textiles**

Once again, this easy was conducted only for the previously washed samples (3077/2023 and 3078/2023). Both samples had the same assay conditions and an average absorption time of over 60 seconds, which means the water didn't penetrate the samples until >60s (the maximum time requirement for this assay). EN 13795-1:2019 and EN 13795-2:2019 have no requirements for this assay.

ESSAY GROUP REQUESTED: **EN 13795-1/2:2019**	HIDROFILIDADE DE TÊXTEIS BRANQUEADOS **AATCC TM79-2010e2(2018)e**

Note. this essay was only conducted for samples 3077/2023 and 3078/2023

Results for sample **3077/2023** (after washing - *see EN ISO 15797:2018*)	
Average absorption time (s)	Relative expanded uncertainty (K=2)
>60	31%

Essay conditions	
Liquid used	Conditioned environment
Grade 3 water	20+/-2ºC e 65+/-4%H.R.

Results for sample **3078/2023** (after washing - *see ISO 6330:2012*)	
Average absorption time (s)	Relative expanded uncertainty (K=2)
>60	31%

Essay conditions	
Liquid used	Conditioned environment
Grade 3 water	20+/-2ºC e 65+/-4%H.R.

Como interpretar este teste?
A amostra foi submetida a >60s, o que significa que a gota de água não penetrou no material até 60 s, tempo máximo de ensaio que a norma indica.

Summary

The results of the assays performed on the original sample (sample 1763/2023) are in accordance with EN 13795-1:2019 and EN 13795-2:2019 for standard performance. For sample 3077/2023, representing 70 industrial wash cycles, the results are in accordance with EN 13795-1:2019 and EN 13795-2:2019 for high performance. Lastly, the results for sample 3078/2023, representing 70 domestic wash cycles, are also in accordance with EN 13795-1:2019 and EN 13795-2:2019 for high performance.

Equilibrium - Lab Certification

Our other certification partner, *Equilibrium*, the Process and Quality Control laboratory tested a provided sample of Shelly ProCare regarding its skin irritation index. You can read the full report sent to IHCare by Equilibrium in the Attachments.

The test performed was an animal irritation, single-exposure test according to the requirements of ISO 10993-23:2021 - Biological evaluation of medical devices. The sample was cut into 2.5cm x 2.5cm squares and moistened with sodium chloride. As a positive control, a solution of 20% sodium lauryl sulfate solution was used; as a negative control sodium chloride was used. The test was performed on 3 rabbits with healthy and undamaged skin, with no restrictions on sex; female rabbits were nulliparous and not pregnant. The moistened samples were applied to the animals' test areas and the application sites were covered with a bandage for 4h. Once the dressings were removed the area was cleaned with lukewarm water. The appearance of the dressing site was registered at 1h, 24h, 48h, and 72h after patch removal. At all these times there were no abnormal symptoms at the contact parts. The primary irritation index was 0.00 at all times, for all application sites, for both erythema and eschar formation and oedema formation, which means our sample is negligible to the skin.
(Test results bellow)

		Skin irritation per time control									
		1h		24h		48h		72h			
Animal nr.	Application site	Erythema and eschar formation	Oedema formation	Erythema and eschar formation	Oedema formation	Erythema and eschar formation	Oedema formation	Erythema and eschar formation	Oedema formation	Irritation score	
1	Left front	0	0	0	0	0	0	0	0	0,00	
	Right rear	0	0	0	0	0	0	0	0	0,00	
	Right front	0	0	0	0	0	0	0	0	0,00	Control Site
	Left rear	0	0	0	0	0	0	0	0	0,00	Control Site
2	Left front	0	0	0	0	0	0	0	0	0,00	
	Right rear	0	0	0	0	0	0	0	0	0,00	
	Right front	0	0	0	0	0	0	0	0	0,00	Control Site
	Left rear	0	0	0	0	0	0	0	0	0,00	Control Site
3	Left front	0	0	0	0	0	0	0	0	0,00	
	Right rear	0	0	0	0	0	0	0	0	0,00	
	Right front	0	0	0	0	0	0	0	0	0,00	Control Site
	Left rear	0	0	0	0	0	0	0	0	0,00	Control Site
		Primary Irritation Index (PII)								0,00	

Latest Tests

Our latest tests, made in September of 2023, with our lab partner, Equilibrium, were regarding the antibacterial and antifungal activity of our newest improved textile, with a bigger thread count, making it even softer and more comfortable than before.

The norms conducted by the lab were:

➔ **ISO 20743:2021 - Antibacterial Activity**

This norm was tested for the normal strains included in its description (*Staphylococcus aureus and Klebsiella pneumoniae*), but also for the strains most frequently causing HAIs (Health Care-Associated Infections), namely *carbapenem-resistant Enterobacteriaceae (CRE)*. and *E.coli*.

For this norm, the results of antibacterial activity(A) fall into values:

- A< 2 → Weak activity (weak ability to prevent/reduce bacterial proliferation)
- 2<A<3 → Significant activity (significant ability to prevent/reduce bacterial proliferation)
- A>3 → Optimal activity (excellent ability to prevent/reduce bacterial proliferation)

Description	Methods	Results
Staphylococcus aureus	ISO 20743:2021	A=2.4
Klebsiella pneumoniae	ISO 20743:2021	A=2
carbapenem-resistant Enterobacteriaceae	ISO 20743:2021	A<2
E.coli	ISO 20743:2021	A<2

These results mean that our product, even after alterations, has a significative antibacterial activity against the bacteria strains predicted in the norm, despite having a low antibacterial activity against the strains most frequently causing HAIs. It's worth to notice that a low antibacterial activity is not the same as no antibacterial activity, it just means that the capacity to prevent bacterial proliferation is lower when compared to other bacterial strains.

➔ **NP EN 14119- Método B2:2005** (equivalent to AATCC TM30-III) - **Antifungal Activity**

This test was conducted in order to guarantee the best performance based on REACH - ECHA standards, the goal is for the result to be an absence of growth visible to the naked eye.
Unfortunately, our results were negative, which means there was growth visible to the naked eye → our textile is not antifungal.
This isn't, however, a major concern since the sheets currently used by healthcare institutions are also not antifungal.
If the recommended washing and drying procedures are followed correctly, there isn't any expected fungal growth.

Attachments

AGÊNCIA NACIONAL DE INOVAÇÃO

sifIDE
Sistema de Incentivos Fiscais à I&D Empresarial

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Diana Filipa Santos Pires
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Data: Lisboa, 29 de outubro de 2021

Assunto: **Reconhecimento de idoneidade da Ihcare – Innovation hospital care, Lda em matéria de investigação e desenvolvimento**

De acordo com o disposto do n.º 1 do Art. 37º-A do Código Fiscal do Investimento, aditado pela Lei nº 114/2017 de 29 de dezembro, vem a Agência Nacional de Inovação reconhecer a idoneidade à Ihcare – Innovation hospital care, Lda, para a prática de atividades de investigação e desenvolvimento no seguinte domínio técnico-científico e áreas de atuação:

Saúde
- Tecnologias avançadas aplicadas à Saúde
- TIC aplicadas à Saúde

Pela ANI – Agência Nacional de Inovação, S.A.,
A Comissão Técnica com competência delegada,

PAULO ALEXANDRE REIS MADEIRA
Assinado de forma digital por PAULO ALEXANDRE REIS MADEIRA
Dados: 2021.11.12 09:19:55 Z

FRANCISCO MANUEL SIMÕES DE MOURA
Digitally signed by FRANCISCO MANUEL SIMÕES DE MOURA
Date: 2021.11.12 10:35:30 Z

SÓNIA MEIRELES RICCA GONÇALVES
Assinado de forma digital por SÓNIA MEIRELES RICCA GONÇALVES
Dados: 2021.11.04 16:00:53 Z

ANI - AGÊNCIA NACIONAL DE INOVAÇÃO, SA.
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Certification partners

EQUILIBRIUM
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